

Complaint

IN THE MATTER OF

**INTEGRA LIFESCIENCES HOLDINGS
CORPORATION**

AND

JOHNSON & JOHNSON

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT

Docket No. C-4624; File No. 171 0084

Complaint, September 26, 2017 – Decision, December 21, 2017

This consent order addresses the \$1 billion acquisition by Integra LifeSciences Holdings Corporation of certain assets of Johnson & Johnson's Codman Neuro division. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by substantially lessening competition in the U.S. markets for intracranial pressure monitoring systems, cerebrospinal fluid collection systems, non-antimicrobial external ventricular drainage catheters, fixed pressure valve shunt systems, and dural grafts. The consent order requires the parties to divest all rights and assets to Natus Medical Incorporated related to Integra's intracranial pressure monitoring systems and fixed pressure valve shunt systems, as well as Codman's cerebrospinal fluid collection systems, non-antimicrobial external ventricular drainage catheters, and dural grafts.

Participants

For the *Commission*: Anne R. Schenof, Danielle Sims, Aylin M. Skroejer and David Von Nirschl.

For the *Respondents*: Jessica Bratten, Patrick English, Amanda Reeves and E. Marcellus Williamson, Latham & Watkins LLP; Jonathan Cheng, Kristin Sanford and Laura Wilkinson, Weil, Gotshal & Manges LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Integra LifeSciences Holdings Corporation ("Integra"), a corporation subject to the jurisdiction

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of the Commission, has agreed to acquire certain assets of the Codman Neuro (“Codman”) division of Respondent Johnson & Johnson, a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45; that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45; and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Integra is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its principal executive offices located at 311 Enterprise Drive, Plainsboro, New Jersey 08536.

2. Respondent Johnson & Johnson is a corporation organized, existing, and doing business under and by virtue of the laws of the state of New Jersey, with its principal executive offices located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

3. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

THE PROPOSED ACQUISITION

4. Pursuant to an Asset Purchase Agreement signed on February 14, 2017, Integra will acquire Codman in a transaction valued at approximately \$1.0 billion (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

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THE RELEVANT MARKETS

5. The relevant lines of commerce in which to analyze the effects of the Acquisition are the development, manufacture, license, marketing, distribution, and sale of point of: (i) intracranial pressure monitoring systems; (ii) cerebrospinal fluid collection systems; (iii) non-antimicrobial external ventricular drainage catheters; (iv) fixed pressure valve shunt systems; and (v) dural grafts.

6. The United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in the relevant lines of commerce.

THE STRUCTURE OF THE MARKETS

7. Integra and Codman are the only significant suppliers of intracranial pressure monitoring systems in the United States. Integra and Codman control approximately 68% and 26% of the market, respectively.

8. Integra and Codman are two of only three major suppliers of cerebrospinal fluid collection systems in the United States. Integra leads the market with approximately 57% market share, and Codman has a market share of approximately 14%. The other leading supplier, Medtronic, accounts for approximately 27% of the market.

9. Integra and Codman are two of only three major suppliers of non-antimicrobial external ventricular drainage catheters in the United States. Integra has a market share of approximately 29% and Codman has a share of approximately 17%. Medtronic is the only other substantial competitor, with a share of approximately 51%.

10. Integra, Codman, and Medtronic are the only three significant suppliers of fixed pressure valve shunts in the United States. Integra and Codman represent 23% and 15% of the market, respectively. Medtronic accounts for 55% market share. Two other firms, Aesculap and Sophysa, hold fringe positions.

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11. Integra is the leading supplier of dural grafts in the United States, with a 66% market share. Medtronic, Codman, and Stryker are the only other significant suppliers, and they account for 11%, 9%, and 8% of the dural grafts market, respectively. Other firms supplying dural grafts have considerably smaller shares.

EFFECTS OF THE ACQUISITION

12. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by eliminating actual, direct, and substantial competition between Integra and Codman in the markets at issue, thereby increasing the likelihood in these markets that: (1) a combined Integra-Codman would be able to unilaterally exercise market power; and (2) customers would be forced to pay higher prices.

CONDITIONS OF ENTRY AND EXPANSION

13. Entry into the relevant markets described in Paragraphs 5 and 6 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the product development, U.S. Food and Drug Administration approval, and market adoption times are lengthy. A potential entrant into the relevant markets would need to establish a sales and marketing infrastructure, proven track record of service, and a robust portfolio of neurosurgical products to drive sales of the relevant products.

VIOLATIONS CHARGED

14. The Asset Purchase Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

15. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the

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Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-sixth day of September, 2017 issues its Complaint against said Respondents.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Integra Lifesciences Holdings Corporation (“Integra”) of certain assets associated with Respondent Johnson & Johnson’s Codman Neuro (“Codman”) division (Integra and Johnson & Johnson hereinafter collectively referred to as “Respondents”), and Respondents having been furnished thereafter with a copy of a draft of the Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

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The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues this Order to Maintain Assets:

1. Respondent Integra is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its principal executive offices located at 311 Enterprise Drive, Plainsboro, New Jersey 08536.
2. Respondent J & J is a corporation organized, existing, and doing business under and by virtue of the laws of the state of New Jersey, with its principal executive offices located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.
3. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Integra” means Integra LifeSciences Holding Corporation; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Integra LifeSciences Holdings Corporation, and the respective directors,

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officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Integra shall include the Transferred Assets.

- B. “J&J” means Johnson & Johnson; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Johnson & Johnson (including, without limitation, Codman Neurosurgery and DePuy Synthes, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Respondent(s)” means Integra and J& J, individually and collectively.
- E. “Decision and Order” means the:
 - 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 - 2. Final Decision and Order following its issuance and service by the Commission in this matter.
- F. “Divestiture Product Business(es)” means the Business of a Respondent (as that Respondent is specified in the definition of each Divestiture Product) within the United States of America related to each of the Divestiture Products to the extent that such Business is owned, controlled, or managed by the Respondent and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondent.
- G. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.

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- H. “Transition Period” means, for each Divestiture Product that is marketed or sold in the United States before the Closing Date, the period beginning on the date this Order to Maintain Assets is issued and ending on the earlier of the following dates: (i) the date on which the relevant Acquirer directs the Respondent(s) to cease the marketing, distribution, and sale of such Divestiture Product(s); (ii) the date on which the relevant Acquirer commences the marketing, distribution, and sale of such Divestiture Product(s); or (iii) the date four (4) months after the Closing Date for such Divestiture Product(s).
- I. “Orders” means the Decision and Order and this Order to Maintain Assets.

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Divestiture Product Assets except for ordinary wear and tear. Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in the Decision and Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the related Divestiture Product Businesses.
- B. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain the operations of

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the related Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the full economic viability, marketability, and competitiveness of such Divestiture Product Businesses and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; High Volume Accounts; end-use customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses. Respondents' responsibilities shall include, but are not limited to, the following:

1. providing each of the respective Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans, and promotional activities for such Divestiture Product Business;
2. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by the Respondents, including, but not limited to, all research, Development, manufacturing, distribution, marketing, and sales expenditures;
3. providing such resources as may be necessary to respond to competition against each of the Divestiture Products and/or to prevent any diminution in sales of each of the Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Product Assets to an Acquirer;
4. providing such resources as may be necessary to maintain the competitive strength and positioning

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of each of the Divestiture Products that were marketed or sold by Respondents prior to the date the Respondents entered the agreement to effect the Acquisition (as such agreement is identified in the definition of Acquisition), at the related High Volume Accounts;

5. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such Divestiture Product Business; and
 6. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such Divestiture Product Business by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. Not later than one (1) day after the date this Order to Maintain Assets is issued by the Commission, for each Divestiture Product that has been marketed or sold prior to the Closing Date, Respondents shall provide to the Proposed Acquirer of that Divestiture Product, for each High Volume Account, a list by either UPC or DI containing the current net price per UPC or DI, *i.e.*, the final price per UPC or DI, charged by the relevant Respondent (as that Respondent is identified in the definition of each Divestiture Product) net of all customer-level discounts, rebates, or promotions, for that Divestiture Product, as of five (5) business days or

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less prior to the date this Order to Maintain Assets is issued.

- E. For each Acquirer of a Divestiture Product, Respondents shall:
1. for a period of twelve (12) months from the Closing Date, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the “Divestiture Product Core Employee Access Period(s);”
 2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to the relevant Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by that Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer’s or Proposed Acquirer’s written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer’s or Proposed

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Acquirer's employees who need such access in connection with the specified and permitted use;

3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and Divestiture Product Assets acquired by that Acquirer, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with a Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, a Respondent shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit a Respondent from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with a Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Divestiture Product(s) and to ensure successful

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execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by a Respondent until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law); and

5. for a period of one (1) year from the Closing Date, not: (i) directly or indirectly solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or (ii) hire any Divestiture Product Employee;

provided, however, a Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with that Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that this Paragraph does not require nor shall be construed to require a Respondent to terminate the employment of any employee or to prevent a Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition;

provided further, however, that a Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts a Respondent on his or her own initiative

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without any direct or indirect solicitation or encouragement from that Respondent.

- F. During the Transition Period, with respect to each Divestiture Product that is marketed or sold in the United States before the Closing Date for that Divestiture Product, Respondents, in consultation with the relevant Acquirer, for the purposes of ensuring an orderly marketing and distribution transition, shall:
1. develop and implement a detailed transition plan to ensure that the commencement of the marketing, distribution, and sale of such Divestiture Products by the Acquirer is not delayed or impaired by the Respondents;
 2. designate employees of Respondents knowledgeable about the marketing, distribution, and sale related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer, and the Monitor (if one has been appointed), for the purposes of assisting in the transfer to the Acquirer of the Business related to the Divestiture Products;
 3. maintain and manage inventory levels of the Divestiture Products in consideration of the marketing and distribution transition to the Acquirer;
 4. continue to market, distribute, and sell the Divestiture Products;
 5. allow the Acquirer access at reasonable business hours to all Confidential Business Information related to the Divestiture Products and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products that contain such Confidential Business Information pending the completed delivery of

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such Confidential Business Information to the Acquirer;

6. to the extent known or available to the specified Respondent, provide the Acquirer with a list of the inventory levels (weeks of supply) in the possession of each customer (*i.e.*, healthcare provider, hospital, group purchasing organization, wholesaler, or distributor) by UPC or DI on a regular basis and in a timely manner;
7. to the extent known by the specified Respondent, provide the Acquirer with anticipated reorder dates for each customer by UPC or DI on a regular basis and in a timely manner; and
8. establish projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the Acquirer in an efficient and timely manner.

G. Pending divestiture of the Divestiture Product Assets, Respondents shall:

1. not use, directly or indirectly, any Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Assets, (ii) other Persons specifically authorized by such Acquirer to receive such

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information, (iii) the Commission, (iv) the Monitor (if any has been appointed) and *except* to the extent necessary to comply with applicable law; and

3. ensure that Confidential Business Information related exclusively to the Divestiture Products is not disseminated among the employees of the Respondents and institute procedures and requirements to ensure that the Respondents employees:
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
 - b. do not solicit, access or use any Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- H. Not later than thirty (30) days from the earlier of (i) the Closing Date or (ii) the date this Order to Maintain Assets is issued by the Commission, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information.
- I. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondents shall provide a copy of the notification to the relevant Acquirer. Respondents shall maintain complete records of all such notifications at that Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with,

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the acknowledgment program. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.

- J. Respondents shall monitor the implementation by its employees and other personnel of all applicable restrictions with respect to Confidential Business Information, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets.
- K. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer; to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic Territory; and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Product Assets except for ordinary wear and tear.

III.**IT IS FURTHER ORDERED** that:

- A. Edward J. Buthusiem shall serve as Monitor to assure that the Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets, and the Remedial Agreements.
- B. No later than one (1) day after the Acquisition Date, Respondents shall enter into the Monitor Agreement that is attached as Appendix I and Confidential Appendix I-1 to the Order to Maintain Assets. The Monitor Agreement shall become effective on the date the Order to Maintain Assets is issued. Respondents shall transfer to and confer upon the Monitor all the

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rights and powers necessary to permit the Monitor to perform his duties and responsibilities in a manner consistent with the purposes of the Orders. Respondents shall assure, and the Monitor Agreement shall provide, that:

1. The Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
3. The Monitor shall serve until the latter of:
 - a. the date the Respondents complete the transfer of all Divestiture Product Assets, and the transfer and delivery of the related Manufacturing Technology, Product Intellectual Property and Product Licensed Intellectual Property;
 - b. the date that each respective Acquirer has obtained all Product Approvals necessary to manufacture and market each Divestiture Product acquired by that Acquirer in the United States of America independently of the Respondents; and
 - c. the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture a Divestiture Product that is being monitored by the Monitor;

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provided, however, that the Monitor's service shall not extend more than four (4) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- C. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to the Respondents' compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor the Respondents' compliance with the Orders.
- D. The Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- E. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.

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- F. Respondents shall report to the Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by each Acquirer with respect to the performance of a Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Orders; *provided, however*, beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph VII.C. of the Decision and Order, and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.
- G. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- H. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- I. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the

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Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.

- J. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- K. The Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as the Monitor pursuant to the Decision and Order.
- L. The Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondents have fully complied with this Order to Maintain Assets, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with the Orders. Respondents shall submit at the same time a copy of its report concerning compliance with the Orders to the Monitor, if any Monitor has been appointed. Respondents shall include in its reports, among other things that are required from time to time, a detailed description of its efforts to comply with the relevant paragraphs of the Orders, including:

- A. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, and (ii) transitional services being provided by the relevant Respondent to the relevant Acquirer; and
- B. a detailed description of the timing for the completion of such obligations.

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provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission on the same timing as, the reports of compliance required to be submitted by Respondents pursuant to the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B. any proposed acquisition, merger, or consolidation of a Respondent; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that Respondents shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of

Order to Maintain Assets

the authorized representative(s) of the Commission and at the expense of that Respondent; and

- B. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the later of:

- A. three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34;
- B. the day after the divestiture of all of the Divestiture Product Assets, as required by and described in the Decision and Order, has been completed;
- C. the day after the Manufacturing Technology related to each Divestiture Product has been provided to the Acquirer in a manner consistent with the Technology Transfer Standards and the Monitor (if one has been appointed), in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers, and other transitions related to the provision of the Manufacturing Technology are complete; or
- D. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

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DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Integra Lifesciences Holdings Corporation (“Integra”) of certain assets associated with Respondent Johnson & Johnson’s Codman Neuro (“Codman”) division (Integra and Johnson & Johnson hereinafter collectively referred to as “Respondents”), and Respondents having been furnished thereafter with a copy of a draft of the Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”) containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of the Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having modified the Decision and Order in certain respects, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

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1. Respondent Integra is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its principal executive offices located at 311 Enterprise Drive, Plainsboro, New Jersey 08536.
2. Respondent Johnson & Johnson is a corporation organized, existing, and doing business under and by virtue of the laws of the state of New Jersey, with its principal executive offices located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.
3. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and this proceeding is in the public interest.

I.

IT IS ORDERED that, as used in the Order, the following definitions shall apply:

- A. “Integra” means Integra LifeSciences Holding Corporation; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Integra LifeSciences Holdings Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Integra shall include the Transferred Assets.
- B. “Johnson & Johnson” means Johnson & Johnson’s directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Johnson & Johnson (including, without limitation, Codman and DePuy Synthes, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

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- C. “Commission” means the Federal Trade Commission.
- D. “Respondent(s)” means Integra and Johnson & Johnson, individually and collectively.
- E. “Acquirer(s)” means the following:
 - 1. Natus, if approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
 - 2. Any other Person approved by the Commission to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. “Acquisition” means Integra’s acquisition of the Transferred Assets pursuant to the Acquisition Agreement.
- G. “Acquisition Agreement” means the Asset Purchase Agreement dated as of February 14, 2017, between Depuy Synthes, Inc. and Integra LifeSciences Holdings Corporation that was submitted by Integra to the Commission in this matter. The Acquisition Agreement is contained in Non-Public Appendix I.
- H. “Acquisition Date” means the date on which Integra acquires any of the Transferred Assets.
- I. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- J. “Application(s)” means all submissions and applications for a Product filed or to be filed by the

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holder, the applicant, and/or the sponsor of a Product with the FDA pursuant to 21 C.F.R. Parts 800 to 898 (entitled “Regulations Subchapter H—Medical Devices”), including, without limitation, the following:

1. Premarket Notification (“510(k) Submission”);
 2. Premarket Approval Application (“PMA”);
 3. Investigational Device Exemption Application (“IDE”);
 4. Device Master File (“MAF”);
 5. Device History File (“DHF”);
 6. Device History Record (“DHR”);
 7. Device Master Record (“DMR”);
 8. authorizations to the holder, applicant, and/or sponsor of a Product from any Third Party to incorporate the information contained in an application or submission held by that Third Party to the FDA into a 510(k) Submission, PMA, or IDE submitted or to be submitted by the holder, applicant, and/or sponsor;
 9. supplements, amendments, and revisions to the abovementioned submissions and applications;
 10. preparatory work, registration dossier, drafts, and data necessary for the preparation of the abovementioned submissions and applications; and
 11. all correspondence between the FDA and the holder, the applicant, and/or the sponsor related to the abovementioned submissions and applications.
- K. “Business” means the research, Development, manufacture, commercialization, distribution,

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marketing, importation, advertisement, and sale of a Product.

- L. “Categorized Assets” means the following assets and rights of the Respondents (identified in the definition of the Divestiture Product), as such assets and rights are in existence as of the date that Respondent signs the Consent Agreement in this matter:
1. all rights to all of the Applications related to the specified Divestiture Products;
 2. all rights to all of the Device Studies related to the specified Divestiture Products;
 3. all Product Intellectual Property related to the specified Divestiture Products that is not Product Licensed Intellectual Property;
 4. all Product Approvals related to the specified Divestiture Products;
 5. all Manufacturing Technology exclusively related to the specified Divestiture Products;
 6. all Marketing Materials related to the specified Divestiture Products;
 7. all Scientific and Regulatory Material related to the specified Divestiture Products;
 8. all Website(s) related exclusively to the specified Divestiture Products;
 9. the content related exclusively to the specified Divestiture Products that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Products;
 10. all Product Development Reports related to the specified Divestiture Products;

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11. at the option of the Acquirer of the specified Divestiture Products, all Product Contracts to the extent related to the specified Divestiture Products; *provided, however*, that for any Product Contract that also relates to any Retained Product(s), Respondents' rights under those Product Contracts continue with regard to the relevant Retained Products.
12. all patient registries related to the specified Divestiture Products, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data, and identification information required to be maintained by the FDA to facilitate the investigation of the precision or accuracy of the specified Divestiture Products;
13. for each specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date:
 - a. a list of all customers for the specified Divestiture Product and a listing of the net sales (in units and dollars) of the specified Divestiture Product to such customers during the one (1) year period immediately prior to the Closing Date, stated on either an annual, quarterly, or monthly basis, including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;
 - b. for each High Volume Account, a list by either UPC or DI containing the following: (i) the net price per UPC or DI as of the Closing Date, *i.e.*, the final price per UPC or DI, charged by

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the specified Respondent net of all customer-level discounts, rebates, or promotions; (ii) the net price per UPC or DI charged by the specified Respondent at the end of each quarter during the one (1) year immediately prior to the Closing Date; (iii) any supply outages by UPC or DI during the one (1) year period immediately prior to the Closing Date the result of which caused the specified Respondent to make a financial payment to the customer or to incur a penalty for a failure to supply;

- c. for each month for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product:
 - i. wholesale acquisition cost; and
 - ii. backorders by UPC or DI as of the Closing Date;

14. a list of each specified Divestiture Product that has had any finished Product batch or lot determined to be out-of-specification during the three (3) year period immediately preceding the Closing Date, and, for each such Divestiture Product: (i) a detailed description of the nonconformity with respect to any out-of-specification batch or lot; (ii) the corrective actions or reworking taken to remediate the cGMP deficiencies in the Divestiture Product; and (iii) to the extent known by the specified Respondent, the employees (whether current or former) responsible for taking such corrective actions or reworking;

15. for each specified Divestiture Product:

- a. to the extent known or available to the specified Respondent, a list of the inventory levels (weeks of supply) in the possession of each customer (*i.e.*, healthcare provider,

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hospital, group purchasing organization, wholesaler, or distributor) as of the date prior to and closest to the Closing Date as is available;

- b. to the extent such records are in existence as of the Closing Date, records of all sales calls, visits, or contacts with current or prospective customers of the Divestiture Product(s) within the one (1) year period immediately preceding the Closing Date;
 - c. to the extent known to the specified Respondent, a summary or description of the discussions related to any potential future sales of the Divestiture Product(s) with current or prospective customers; and
 - d. to the extent known by the specified Respondent, any pending reorder dates for a customer as of the Closing Date;
16. at the option of the Acquirer of the specified Divestiture Products and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging and labeling materials (including FDA-approved Product labeling and currently used or planned product inserts), work-in-process, replacement and spare parts, operating supplies and inventory on consignment, and finished and semi-finished products used or intended for use in the specified Divestiture Product and, for a limited period of time sufficient for that Acquirer to market or sell any finished or semi-finished inventory as of the Closing Date and to the extent required for that specific purpose, a license to the corporate names or corporate trade dress of the specified Respondent, or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or

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companies owned or controlled by that Respondent or the related corporate logos thereof; or general registered images or symbols by which that Respondent can be identified or defined that the Respondent has been using on the final Product or its packaging prior to the Closing Date;

17. the quantity and delivery terms in all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
18. at the option of the Acquirer of the specified Divestiture Product, the right to fill any or all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date; and
19. all of a Respondent's books, records, and files related to the foregoing;

provided, however, that "Categorized Assets" shall not include: (i) documents relating to a Respondent's general business strategies or practices relating to the conduct of its Business outside of the Divestiture Products, where such documents do not discuss with particularity the specified Divestiture Product; (ii) information that is exclusively related to the Retained Products; and (iii) all Product Licensed Intellectual Property;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Divestiture Product and to Retained Products or Businesses of the specified Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which any Respondent has a legal obligation to retain the original copies, that Respondent shall be required to provide

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only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the Respondents shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the Respondents provide the Acquirer with the above-described information without requiring a Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

- M. “Cerebrospinal Fluid Collection Systems” means all Products researched, Developed, in Development, marketed, sold, owned, or controlled by Johnson & Johnson (prior to Acquisition) that are a part of, used with, or intended to be used with, Codman’s cerebrospinal fluid collection systems product line, listed by device name and 510(k) Number in Non-Public Appendix III.A., and all improvements or modifications thereto.
- N. “Cerebrospinal Fluid Collection Systems Assets” means all rights, title, and interest in and to all assets related to the Business of Johnson & Johnson related to each of the Cerebrospinal Fluid Collection Systems, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Cerebrospinal Fluid Collection Systems.
- O. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act (21 C.F.R. 820), as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- P. “Closing Date” means, as to each Divestiture Product, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey

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assets related to such Divestiture Product to an Acquirer pursuant to this Order.

Q. “Confidential Business Information” means all information owned by, or in the possession or control of, a Respondent that is not in the public domain and to the extent that it is directly related to the conduct of the Business related to a Divestiture Product(s). The term “Confidential Business Information” *excludes* the following and the Respondents are not required to submit this information to an Acquirer:

1. information relating to a Respondent’s general business strategies or practices that does not discuss with particularity the Divestiture Products;
2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);
3. information that is contained in documents, records, or books of a Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and
4. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

R. “Contract Manufacture” means the following:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer; or
2. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the components or packaging of a

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Contract Manufacture Product on behalf of an Acquirer.

- S. “Contract Manufacture Products” means the following Products, individually and collectively:
1. Intracranial Pressure Monitors;
 2. Ventricular Tunnel Catheters;
 3. Cerebrospinal Fluid Collection Systems;
 4. Non-Antimicrobial External Ventricular Drainage Catheters;
 5. Fixed Pressure Valve Shunt Systems;
 6. Dural Graft Products; and
 7. Cranial Access Kits.
- T. “Copyrights” means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the United States of America, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and all educational materials for the sales force; copyrights in all preclinical, clinical, and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing, or sale of that Product, including all copyrights in raw data relating to Device Studies of that Product, all case report forms relating thereto, and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports, and statistical programs (if any) used for marketing and sales research; all copyrights in

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customer information, promotional and marketing materials, that Product's sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of a Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

- U. "Cranial Access Kits" means all Products researched, Developed, in Development, marketed, sold, owned, or controlled by Integra (prior to Acquisition) that are a part of, used with, or intended to be used with, Integra's cranial access kits product line, listed by device name and SKU Number in Appendix IV, and all improvements or modifications thereto.
- V. "Cranial Access Kits Supply Agreement" means the *Supply Agreement* by and between Integra LifeSciences Holdings Corporation and Natus Medical Incorporated, dated as of the Closing Date.
- W. "Current Operation Condition" means that, as of the date of delivery to the Acquirer, the equipment meets or exceeds all current operational (including, without limitation, electrical), functional, productive and manufacturing capabilities required to manufacture the Fixed Pressure Valve Shunt Systems within the United

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States and meets all current U.S. Agency-approved protective workplace safety standards for the operation of such equipment by workers.

- X. “Development” means all research and development activities, including, without limitation the following: design; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; mechanical properties testing; performance testing; safety testing; conducting Device Studies for the purpose of obtaining or achieving any and all approvals, licenses, registrations, or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals). “Develop” means to engage in Development.
- Y. “Device Study(ies)” means a controlled study of the quality, safety, efficacy, precision, or accuracy of a Product (including any or all such investigations conducted *in vitro*, *in vivo*, and/or *in silico*) and includes, without limitation, such studies as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other such study used in research and Development of a Product.
- Z. “DI” means that mandatory portion of the unique device identifier (*i.e.*, an identifier number that identifies a device through its distribution and use by meeting the requirements of 21 C.F.R. 830.20) that identifies the specific version or model of a device and the labeler of that device.
- AA. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance, service, or Contract Manufacture Product. “Direct Cost” to the Acquirer for (1) its use of any of a Respondent’s employees’ labor shall not

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exceed the average hourly wage rate for such employee and (2) any Contract Manufacture Product shall expressly exclude any intracompany business transfer profit;

provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.

BB. “Divestiture Agreement(s)” means the following:

1. *Asset Purchase Agreement* by and between Integra LifeSciences Holdings Corporation and Natus Medical Incorporated, dated as of September 8, 2017;
2. *Integra Shunts Transitional Supply Agreement* by and between Integra LifeSciences Holdings Corporation and Natus Medical Incorporated, to be executed on or before the Closing Date;
3. *Integra Transitional Services Agreement* by and between Integra LifeSciences Holdings Corporation and Natus Medical Incorporated, to be executed on or before the Closing Date;
4. *Supply Agreement* by and between Integra LifeSciences Holdings Corporation and Natus Medical Incorporated, to be executed on or before the Closing Date;
5. *Transition Manufacturing Agreement* by and between Integra LifeSciences Holdings Corporation and Natus Medical Incorporated, to be executed on or before the Closing Date;
6. *Transition Manufacturing Services Agreement* by and between Depuy Synthes, Inc. and Natus

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Medical Incorporated, to be executed on or before the Closing Date;

7. *Transition Services Agreement* by and between Depuy Synthes, Inc. and Natus Medical Incorporated, to be executed on or before the Closing Date; and
8. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreement.

The Divestiture Agreements are contained in Non-Public Appendix II. The Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

CC. "Divestiture Product(s)" means the following, individually and collectively:

1. Intracranial Pressure Monitoring Systems;
2. Cerebrospinal Fluid Collection Systems;
3. Non-Antimicrobial External Ventricular Drainage Catheters;
4. Fixed Pressure Valve Shunt Systems; and
5. Dural Graft Products.

DD. "Divestiture Product Assets" means the following, individually and collectively within the United States of America:

1. Intracranial Pressure Monitoring Systems Assets;
2. Cerebrospinal Fluid Collection Systems Assets;

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3. Non-Antimicrobial External Ventricular Drainage Catheters Assets;
 4. Fixed Pressure Valve Shunt Systems Assets; and
 5. Dural Graft Product Assets.
- EE. “Divestiture Product Core Employees” means the Sales and Marketing Employees, Research and Development Employees, and the Manufacturing Employees.
- FF. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up, and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Manufacturing Technology used in the manufacture of the specified Divestiture Product(s) that is also used in the manufacture of Retained Products (*i.e.*, Manufacturing Technology that is used in, but not exclusively used in, the manufacture of the Divestiture Product(s) being acquired by a particular Acquirer) that was owned, licensed, held, or controlled by a Respondent:
1. to research and Develop the specified Divestiture Product(s) for marketing, distribution, or sale within the United States of America;
 2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Product(s) within the United States of America;
 3. to import or export the specified Divestiture Product(s) to or from the United States of America to the extent related to the marketing, distribution, or sale of the specified Divestiture Products in the United States of America; and
 4. to have the specified Divestiture Product(s) made anywhere in the world for distribution or sale

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within, or import into the United States of America;

provided, however, that for any Product Licensed Intellectual Property or Manufacturing Technology that is the subject of a license from a Third Party entered into by a Respondent prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to that Respondent.

GG. “Divestiture Product Releasee(s)” means the following Persons:

1. the Acquirer for the assets related to a particular Divestiture Product;
2. any Person controlled by or under common control with that Acquirer; and
3. any Manufacturing Designee(s), licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.

HH. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.

II. “Domain Name” means the domain name(s) (uniform resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however,* “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Trademarks required to be divested.

JJ. “Dural Graft Product(s)” means all Products researched, Developed, in Development, marketed, sold, owned, or controlled by Johnson & Johnson (prior to the Acquisition) that are a part of, used with, or intended to be used with, the Duraform® product

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line, listed by device name and 510(k) Number in Non-Public Appendix III.B., and all improvements or modifications thereto.

KK. “Dural Graft Product Assets” means all rights, title, and interest in and to all assets related to the Business of Johnson & Johnson related to each of the Dural Graft Products, to the extent legally transferable, including, without limitation, the following:

1. the Categorized Assets related to the Dural Graft Products; and
2. all U.S. rights and assets to the *Supply Agreement* between Depuy Synthes Products, Inc. and Lyophilization Services of New England, Inc.

LL. “Facility Assets” means all of Respondent Integra’s rights, title, and interests in and to the following:

1. real property at the specified location, including all rights, title, and interests in and to owned or leased land and all improvements thereon, including buildings, fixtures, improvements, easements, rights of way, appurtenances, and the rights and privileges appertaining thereto (“Facility”);
2. all Manufacturing Equipment related to the Divestiture Product Assets located at the Facility;
3. all other equipment, machinery, tools, spare parts, vehicles, personal property, furniture, fixtures, and supplies related to the Divestiture Product Assets located at the Facility;
4. all other tangible property, owned, leased or operated on or behalf of a Respondent, and related to the Divestiture Product Assets, located at the Facility; and
5. to the extent transferable by Law, all permits, registrations, and applications to or from a

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Government Entity related to the Respondent's use of the Facility.

- MM. "Fixed Pressure Valve Shunt Systems" means all Products researched, Developed, in Development, marketed, sold, owned, or controlled by Integra (prior to the Acquisition) that are a part of, used with, or intended to be used with, the Novus™, UltraVS™, Contour-Flex™, Equi-Flow™, DPT™ (sold using the Integra name), LPV II™ product lines and lumbar shunts, listed by device name and 510(k) Number in Non-Public Appendix III.C., and all improvements or modifications thereto.
- NN. "Fixed Pressure Valve Shunt Systems Assets" means all rights, title, and interest in and to all assets related to the Business of Integra related to each of the Fixed Pressure Valve Shunt Systems, to the extent legally transferable, including, without limitation, the following:
1. the Fixed Pressure Valve Shunt Systems Equipment; and
 2. the Categorized Assets related to the Fixed Pressure Valve Shunt Systems.
- OO. "Fixed Pressure Valve Shunt Systems Equipment" means all equipment in Current Operation Condition used in the production of Fixed Pressure Valve Shunt Systems, listed by product name and location of facility in Non-Public Appendix III.F., and all improvements or modifications thereto.
- PP. "Government Entity" means any Federal, state, local, or non-U.S. government; any court, legislature, government agency, or government commission; or any judicial or regulatory authority of any government.
- QQ. "High Volume Account(s)" means any healthcare provider, group purchasing organization, hospital, wholesaler, or distributor whose annual or projected

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annual purchase amounts, in units or in dollars, of a Divestiture Product in the United States of America from a Respondent, was or was forecasted (prior to the public announcement of the Acquisition and subsequent divestiture) to be among the top twenty (20) highest such purchase amounts of that Respondent's total sales of that Divestiture Product to U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (iv) for forecasts of purchases of the Divestiture Product, the quarter immediately following the Closing Date.

- RR. "Intracranial Pressure Monitors" are one of the components of Intracranial Pressure Monitoring Systems.
- SS. "Intracranial Pressure Monitoring Systems" means all Products researched, Developed, in Development, marketed, sold, owned, or controlled by Integra that are a part of, used with, or intended to be used with, the Camino® product line, including, without limitation, Intracranial Pressure Monitors and catheters, including Ventricular Tunnel Catheters, listed by device name and 510(k) Number in Non-Public Appendix III.D., and all improvements or modifications thereto.
- TT. "Intracranial Pressure Monitoring Systems Assets" means all rights, title, and interest in and to all assets related to the Business of Integra related to each of the Intracranial Pressure Monitoring Systems, to the extent legally transferable, including, without limitation, the following:
1. the Categorized Assets related to the Intracranial Pressure Monitoring Systems; and

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2. the Intracranial Pressure Monitoring Systems
Product Facility.

- UU. “Intracranial Pressure Monitoring Systems Product Facility” means all the Facility Assets located at 5955 & 5965 Pacific Center Boulevard, San Diego, California 92121.
- VV. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- WW. “Manufacturing Designee” means any Person other than a Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- XX. “Manufacturing Equipment” means all fixtures, equipment (including, without limitation, technical equipment, lab equipment, and computers), and machinery that is being used or has been used at any Facility that is subject to transfer to an Acquirer pursuant to this Order at any time since the Respondents entered into the Acquisition Agreement, in the research, Development or manufacture of a Divestiture Product and that is suitable for use in the research, Development, or manufacture of a Divestiture Product as of the Closing Date.
- YY. “Manufacturing Employees” means all full-time, part-time, or contract employees of a Respondent who have directly participated in any of the following: (i) defining the commercial manufacturing process, (ii) confirming that the manufacturing process is capable of reproducible commercial manufacturing, (iii) formulating the manufacturing process performance qualification protocol, (iv) controlling the manufacturing process to assure performance Product quality, (iv) assuring that during routine manufacturing the process remains in a state of control, (v) collecting and evaluating data for the purposes of providing scientific evidence that the manufacturing process is

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capable of consistently delivering quality Products, (vi) managing the operation of the manufacturing process, or (vii) managing the technological transfer of the manufacturing process to a different facility, with respect to the Manufacturing Technology of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

ZZ. “Manufacturing Technology” means all technology, trade secrets, know-how, designs, ideas, concepts, and proprietary information (whether patented, patentable, or otherwise) owned by the Respondent (identified in the definition of the respective Divestiture Product) to manufacture each specified Divestiture Product, including, but not limited to, the following:

1. all product specifications, product designs and design protocols, including without limitation, the exact combination, design, array, and identity and specifications of all components that achieve a particular set of application and end-use characteristics in a final Product;
2. to the extent applicable to the specified Divestiture Product, antibody generation and reagent formulation;
3. manufacturing processes, analytical methods, flow diagrams, and other related manuals and drawings;
4. standard operating procedures;
5. quality assurance and control procedures;
6. control history;
7. research and Development records;

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8. annual product reviews;
9. supplier lists;
10. labeling and product manuals;
11. manuals and technical information provided to employees, customers, distributors, suppliers, agents, and licensees, including, without limitation, manufacturing, equipment and engineering manuals and drawings;
12. repair and performance records related to the Manufacturing Equipment for the two (2) year period immediately preceding the Closing Date;
13. records related to the protective workplace safety standards related to the Manufacturing Equipment for the two (2) year period immediately preceding the Closing Date;
14. audits of manufacturing methods for the Products conducted by any Agency; and
15. all other information related to the manufacturing process.

AAA. "Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the United States of America as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of dollars and/or units for each month, quarter, or year), sales forecasting models, educational materials, advertising and display materials, speaker lists,

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promotional and marketing materials, Website content, and artwork for the production of packaging components, television masters, and other similar materials related to the specified Divestiture Product.

- BBB. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- CCC. “Natus” means Natus Medical Incorporated, a corporation organized, existing, and doing business under and by virtue of the state of Delaware with its principal executive offices located at 6701 Koll Center Parkway, Suite 120, Pleasanton, California 94566.
- DDD. “Non-Antimicrobial External Ventricular Drainage Catheters” means all Products researched, Developed, in Development, marketed, sold, owned, or controlled by Johnson & Johnson (prior to Acquisition) that are a part of, used with, or intended to be used with, Codman’s non-antimicrobial external ventricular drainage catheter product line, listed by device name and 510(k) Number in Non-Public Appendix III.E., and all improvements or modifications thereto.
- EEE. “Non-Antimicrobial External Ventricular Drainage Catheters Assets” means all rights, title, and interest in and to all assets related to the Business of Johnson & Johnson related to each of the Non-Antimicrobial External Ventricular Drainage Catheters, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Non-Antimicrobial External Ventricular Drainage Catheters.
- FFF. “Orders” means this Decision and Order and the related Order to Maintain Assets.
- GGG. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.

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HHH. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.

III. “Patent(s)” means all patents and patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention, and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.

JJJ. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups, or affiliates thereof.

KKK. “Product(s)” means any medical device as defined by the FDA pursuant to the United States Federal Food, Drug, and Cosmetic Act (*i.e.*, any instrument, apparatus, appliance, software, material, or other article, whether used alone or in combination, including the software intended by its holder, applicant, and/or sponsor to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application) which is:

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them;
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or

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3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

LLL. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any Application related to that Product.

MMM. “Product Contracts” means all contracts or agreements:

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from a Respondent;
2. pursuant to which a Respondent has as of the Closing Date the ability to independently purchase the raw materials, inputs or component(s) from any Third Party, for use in connection with the specified Divestiture Product;
3. relating to any Device Studies involving the specified Divestiture Product;

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4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the specific marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product in finished form in order to provide it to a Respondent;
7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the assembly or packaging of the specified Divestiture Product;
8. pursuant to which a Third Party provides the Manufacturing Technology related to the specified Divestiture Product to a Respondent;
9. pursuant to which a Third Party collaborates with a Respondent in the research and development of any Manufacturing Technology related to the specified Divestiture Product;
10. pursuant to which a Third Party is licensed by a Respondent to use the Manufacturing Technology related to the specified Divestiture Product;
11. constituting confidentiality agreements involving the specified Divestiture Product;
12. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
13. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the specified Divestiture Product to a Respondent

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including, but not limited to, consultation arrangements;

14. pursuant to which any Third Party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of the specified Divestiture Product or the Business related to such Divestiture Product;
15. pursuant to which a Respondent leases buildings or equipment that is subject to transfer to the Acquirer pursuant to this Order; and/or
16. pursuant to which a Respondent licenses Software related to the specified Divestiture Product;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), a Respondent shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

NNN. "Product Development Reports" means:

1. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from, or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;
2. annual and periodic reports related to the above-described Application(s), including any safety update reports;
3. FDA-approved Product labeling related to the specified Divestiture Product;
4. currently used or planned product package inserts related to the specified Divestiture Product;

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5. FDA-approved circulars and information related to the specified Divestiture Product;
6. adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of accuracy related to the specified Divestiture Product;
7. summary of Product complaints from physicians or clinicians related to the specified Divestiture Product;
8. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies, and other documents related to such recalls;
9. investigation reports and other documents related to any out of specification results for any impurities or defects found in the specified Divestiture Product;
10. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including, without limitation, identification and sources of impurities or defects;
11. reports of vendors of the components, active pharmaceutical ingredients, excipients, packaging components, and detergents used to produce the specified Divestiture Product that relate to the design, specifications, degradation, chemical interactions, testing, and historical trends of the production of the specified Divestiture Product;
12. analytical methods development records related to the specified Divestiture Product;
13. manufacturing batch or lot records related to the specified Divestiture Product;

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14. stability testing records related to the specified Divestiture Product;
15. change in control history related to the specified Divestiture Product; and
16. executed validation (including design validation and process validation) and qualification protocols and reports related to the specified Divestiture Product.

OOO. “Product Employee Information” means the following, for each Divestiture Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each Divestiture Product Core Employee; and
2. with respect to each such employee, the following information:
 - a. the date of hire and effective service date;
 - b. job title or position held;
 - c. the base salary or current wages;
 - d. the most recent bonus paid, aggregate annual compensation for the relevant Respondent’s last fiscal year, and current target or guaranteed bonus, if any;
 - e. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
3. at the Acquirer’s option or the Proposed Acquirer’s option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

PPP. “Product Intellectual Property” means all of the following intellectual property related to a Divestiture

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Product (other than Product Licensed Intellectual Property) that is owned, licensed, held, or controlled by a Respondent as of the Closing Date:

1. Patents;
2. Copyrights;
3. Software;
4. Trademarks;
5. Trade Dress;
6. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information; and
7. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof, and to bring suit against a Third Party for the past, present, or future infringement, misappropriation, dilution, misuse, or other violation of any of the foregoing;

provided, however, that “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Integra”, “Johnson & Johnson”, “Codman”, or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by a Respondent or the related corporate logos thereof; or general registered images or symbols by which Integra or Johnson & Johnson can be identified or defined.

QQQ. “Product Licensed Intellectual Property” means all of the following intellectual property related to a Divestiture Product that is owned, licensed, held, or controlled by a Respondent as of the Closing Date, as follows:

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1. Patents that are related to a Divestiture Product that a Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active Application; and
2. Copyrights, Software, Trademarks, Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the United States of America to limit the use or disclosure thereof, that are related to a Divestiture Product and that a Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued or withdrawn) Application as of the Acquisition Date.

RRR. “Proposed Acquirer” means a Person proposed by a Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed pursuant to this Order.

SSS. “Remedial Agreement(s)” means the following:

1. any agreement between a Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including, without limitation, any agreement to supply specified Products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;

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2. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of that Respondent related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
3. any agreement between a Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including, without limitation, any agreement by that Respondent to supply specified Products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of that Respondent related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

TTT. "Research and Development Employees" means all full-time, part-time, and contract employees of a Respondent who have directly participated in the research, Development, regulatory approval process, or Device Studies of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight

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of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

UUU. “Retained Product(s)” means any Product(s) other than a Divestiture Product.

VVV. “Sales and Marketing Employees” means all full-time, part-time, and contract employees of a Respondent whose primary work responsibilities were in the Business of the Divestiture Products within the eighteen (18) month period immediately prior to the Closing Date and who directly have participated in the sales, marketing, or technical support (including installation) of the specified Divestiture Product directly to distributors or end-use customers, including, without limitation, the regional sales managers.

WWW. “Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and clinical study materials and information.

XXX. “Software” means computer programs related to the Business of the specified Divestiture Product, including all software implementations of algorithms, models, and methodologies whether in source code or object code form, databases and compilations, including any and all data and collections of data, all documentation, including user manuals and training materials, related to any of the foregoing, and the content and information contained on any Website; *provided, however*, that “Software” does not include software that is readily purchasable or licensable from sources other than the Respondents and which has not been modified in a manner material to the use or function thereof (other than user preference settings).

YYY. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer

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pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*:

1. designating employees of a Respondent knowledgeable about the Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Monitor (if one has been appointed), for the purpose of effecting such delivery *unless* such Persons are hired by the Acquirer;
2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer to the extent that any such technology is either (i) not maintained and fully available at a facility that is being transferred to the Acquirer pursuant to this Order or (ii) not maintained and fully available at a facility operated by the Acquirer's Manufacturing Designee;
3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee to the extent that any such technology is either (i) not maintained and fully available at a facility that is being transferred to the Acquirer pursuant to this Order or (ii) not maintained and fully available at a facility operated by the Acquirer's Manufacturing Designee;

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4. permitting employees of the relevant Acquirer to visit the Respondent's facility from which the Divestiture Product will be transferred for the purposes of evaluating and learning the manufacturing process of such Divestiture Product and/or discussing the process with employees of a Respondent involved in the manufacturing process (including, without limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, and validation of the manufacturing of the Divestiture Product at the Respondent's facility); and
 5. to the extent that Persons with the relevant knowledge remain employees of a Respondent (*i.e.*, are not hired by the Acquirer), providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
 - a. manufacture the specified Divestiture Product in the quality and quantities achieved by a Respondent, or the manufacturer and/or developer of such Divestiture Product;
 - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
 - c. receive, integrate, and use all such Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.
- ZZZ. "Third Party(ies)" means any non-governmental Person other than the following: a Respondent; or an Acquirer of particular assets or rights pursuant to this Order.

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- AAAA. “Trade Dress” means the current trade dress of a Product, including but not limited to, Product packaging and the lettering of the Product trade name or brand name.
- BBBB. “Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof), and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.
- CCCC. “Transferred Assets” means the properties of Johnson & Johnson set forth or described as Transferred Assets in the Acquisition Agreement.
- DDDD. “Transition Services” means technical services, personnel, assistance, training, and other logistical, administrative and transitional support as required by an Acquirer and approved by the Commission to facilitate the transfer of the Divestiture Product Assets from the Respondents to the Acquirer, including, but not limited to, services, training, personnel, and support related to: audits, finance and accounting, accounts receivable, accounts payable, employee benefits, payroll, pensions, human resources, information technology and systems, maintenance and repair of facilities and equipment, manufacturing, purchasing, quality control, research and Development support, technology transfer, regulatory compliance, sales and marketing, customer service, and supply chain management and customer transfer logistics.
- EEEE. “Transition Services Agreement(s)” means any agreement(s) that receives the prior approval of the Commission between the Respondents and an Acquirer to provide, at the option of the Acquirer, Transition Services (or training for the Acquirer to provide services for itself) necessary to transfer the Divestiture Product Assets to the Acquirer in a manner consistent with the purposes of this Order.

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FFFF. “United States of America” means the United States of America, and its territories, districts, commonwealths, and possessions.

GGGG. “UPC” means the Universal Product Code (*i.e.*, the product identifier used to identify an item sold at retail in the United States of America).

HHHH. “Ventricular Tunnel Catheters” are one of the components of Intracranial Pressure Monitoring Systems.

III. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by a Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Divestiture Product Assets and grant the Divestiture Product Licenses related to the Divestiture Products, absolutely and in good faith, to Natus pursuant to, and in accordance with, the Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Natus or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Divestiture Product Assets is

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incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Divestiture Product Assets to Natus prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Natus is not an acceptable purchaser of any of the Divestiture Product Assets, then Respondents shall immediately rescind the transaction with Natus in whole or in part, as directed by the Commission, and shall divest the relevant Divestiture Product Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, that if Respondents have divested the Divestiture Product Assets to Natus prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Divestiture Product Assets to Natus (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Closing Date for each respective Divestiture Product, Respondents shall provide the Acquirer with the opportunity to review all contracts or agreements that are Product Contracts related to the Divestiture Products being acquired by that Acquirer for the purposes of the Acquirer's determination whether to assume such contracts or agreements.

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- C. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the Divestiture Product Assets to an Acquirer, and to permit the relevant Acquirer to continue the Business of the Divestiture Products being acquired by that Acquirer;

provided, however, Respondents may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product Assets has executed all such agreements directly with each of the relevant Third Parties, and

provided, further, that to the extent such consents and waivers cannot be secured prior to the Closing Date, Respondents agree to cooperate and provide Acquirer with assistance in securing such consents and waivers for a period of eighteen (18) months following the Closing Date.

- D. Respondent Integra shall:

1. Deliver the Fixed Pressure Valve Shunt Systems Equipment to the Acquirer in Current Operating Condition; *provided however,* that, subject to the consent of the Acquirer on a piece-by-piece basis, Respondents, at Respondents' own expense, may substitute equipment in Current Operating Condition that:
 - a. is suitable for the same use as the particular piece of Fixed Pressure Valve Shunt Systems Equipment that is the subject of the proposed substitution; and
 - b. meets or exceeds the operational, functional, productive, and manufacturing capabilities of the particular piece of Fixed Pressure Valve Shunt Systems Equipment that is the subject of the proposed substitution; and

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2. At the Acquirer's option, provide such technical assistance as is necessary to integrate the Fixed Pressure Valve Shunt Systems Equipment (or any equipment substituted pursuant to the immediately preceding Paragraph) in the Acquirer's chosen facility for use in the manufacture of the Fixed Pressure Valve Shunt Systems.

E. Respondents shall:

1. submit to the Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
2. deliver or provide direct electronic access that is fully accessible by the Acquirer to all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
 - a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to the relevant Acquirer, provide that Acquirer and the Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

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4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Products, (ii) other Persons specifically authorized by that Acquirer to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed) and *except* to the extent necessary to comply with applicable Law;
6. ensure that Confidential Business Information related exclusively to the Divestiture Products is not disseminated among the employees of the Respondents; and
7. after the delivery of the Confidential Business Information to Acquirer of the particular Divestiture Products and upon request of that Acquirer, destroy any copies of Confidential Business Information exclusively related to the particular Divestiture Products acquired by that Acquirer (other than electric copies of Confidential Business Information created as a result of automatic back-up procedures) within thirty (30) days of such request except as otherwise agreed to between the Respondents and the Acquirer or to the extent necessary to comply with applicable Law;

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provided, however, that Respondents shall be allowed to retain and use copies of Confidential Business Information, in the ordinary course and outside of the United States of America, in connection with Retained Products, or Businesses related to Divestiture Products, that Respondents can demonstrate relate to such Retained Products or Businesses related to such Retained Products.

- F. Respondents shall provide, or cause to be provided, to the Acquirer in a manner consistent with the Technology Transfer Standards the following:
1. all Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and
 2. all rights to all Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to a Respondent related to the Divestiture Product(s) being acquired by that Acquirer.

Respondents shall obtain any consents from Third Parties required to comply with this provision. Respondents shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each

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such release, Respondents shall provide a copy of the release to that Acquirer.

- G. Respondents shall, at the option of the Acquirer, and subject to the prior approval of the Commission, provide Transition Services to the Acquirer pursuant to a Transition Services Agreement for a period of (1) year following the Closing Date, with an opportunity to extend for up to one (1) year at the option of the Acquirer; *provided, however*, that such Agreement shall provide that (1) the Acquirer may terminate the Agreement at any time, without cost or penalty to the Acquirer, upon commercially reasonable notice to Respondents; and (2) at the Acquirer's request, Respondents shall file with the Commission any request for prior approval for any additional extension of the term of a Transition Services Agreement as provided in this Paragraph (*i.e.*, in addition to the initial term plus an extension at the option of the Acquirer). The Transition Services provided pursuant to a Transition Services Agreement shall be at no greater than Respondents' Direct Costs for such personnel, technical support, assistance, training, and other services as are necessary to transfer the Divestiture Product Assets to the Acquirer in a manner consistent with the purposes of this Order.
- H. Respondents shall employ a staff of sufficient size, training, and expertise as is necessary to complete all of the transfers of the Manufacturing Technology to each of the Acquirers in a timely manner and to ensure that the Acquirer has sufficient assistance from Respondents to manufacture the Divestiture Products being acquired by that Acquirer in commercial quantities, and in a manner consistent with cGMP at a facility chosen by the Acquirer.
- I. For each Contract Manufacture Product, Respondents shall:
 - 1. upon reasonable written notice and request from the Acquirer to Respondent Integra, Contract

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Manufacture and deliver, or cause to be manufactured and delivered, to the Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Direct Cost, for a period of time sufficient to allow the Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished product independently of Respondent Integra, and to secure sources of supply of the components listed in Application(s) of a Respondent from Persons other than Respondent Integra;

2. make representations and warranties to the Acquirer that the Contract Manufacture Product(s) supplied by Respondent Integra pursuant to a Remedial Agreement meet the relevant Agency-approved specifications;
3. for each Contract Manufacture Product to be marketed or sold in the United States of America, the supplying Respondent shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of any Contract Manufacture Product supplied to the Acquirer pursuant to a Remedial Agreement by that Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving the supplying Respondent prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the supplying Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the supplying Respondent's responsibilities to supply each Contract Manufacture Product in the manner required by this Order;

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provided further, however, that this obligation shall not require such Respondent to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the supplying Respondent to the Acquirer in an agreement to Contract Manufacture;

provided further, however, that the indemnification provisions of this Paragraph II.I.3. shall not apply to any losses alleged to have resulted from the failure of any component included in any Cranial Access Kit to meet cGMP.

4. give *pro rata* priority to supplying a Contract Manufacture Product to the Acquirer over manufacturing and supplying of Products for the supplying Respondent's own use or sale;
5. agree to hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of any Contract Manufacture Product to be delivered in a timely manner *unless* (i) the supplying Respondent can demonstrate that the failure was beyond the control of that Respondent and in no part the result of negligence or willful misconduct by that Respondent, and (ii) the supplying Respondent is able to cure the supply failure not later than thirty (30) days after the receipt of notice from the Acquirer of a supply failure;
6. during the term of any agreement to Contract Manufacture, upon written request of that Acquirer or the Monitor (if any has been appointed), make available to the Acquirer and the Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;

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7. for each Contract Manufacture Product for which the supplying Respondent purchases the component(s) from a Third Party, provide that Acquirer with the actual price paid by the supplying Respondent for each component(s) used to manufacture that Contract Manufacture Product;
8. for each Contract Manufacture Product for which the supplying Respondent is the source of the component(s), not charge the Acquirer any intracompany transfer profit for such component(s) in calculating the total price for the final finished Contract Manufacture Product to the Acquirer, and assure such charges shall only reflect the supplying Respondent's actual cost;
9. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);
10. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture;
11. not be entitled to terminate any agreement to Contract Manufacture due to an Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency Law;
12. shall notify the Commission at least sixty (60) days prior to terminating any agreement with an Acquirer to Contract Manufacture for any reason, and shall submit at the same time a copy of such notice to the Monitor; and

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13. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of the supplying Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the Contract Manufacture Products acquired by that Acquirer in the same quality achieved by, or on behalf of, a Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of the supplying Respondent and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products.

The foregoing requirements to Contract Manufacture shall remain in effect with respect to each Contract Manufacture Product until the earliest of: (i) the date the Acquirer (or the Manufacturing Designee(s) of that Acquirer) is approved by the FDA to manufacture such Contract Manufacture Product for sale in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of the supplying Respondent; (ii) the date the Acquirer notifies the Commission and the supplying Respondent of its intention to abandon its efforts to manufacture the relevant Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the relevant Contract Manufacture Product; or, for any Contract Manufacturing Product, excluding Crainial Access Kits, (iv) five (5) years after the Closing Date.

- J. Respondents shall designate employees of Respondents knowledgeable about the marketing,

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distribution, warehousing, and sale (including administrative logistics of sales to the respective High Volume Accounts) related to each of the Divestiture Products to assist the Acquirer, in the transfer and integration of the Business related to the Divestiture Products into that Acquirer's business *unless* such employees of the Respondents are hired by that Acquirer in connection with the Acquirer's acquisition of the Divestiture Product(s).

- K. Respondents shall require, as a condition of continued employment post-divestiture of the Divestiture Product Assets, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date, and each employee that has responsibilities related to the marketing or sales of those Retained Products that perform the same or similar function as the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of the Respondents (other than as necessary to comply with the requirements of this Order).
- L. Not later than thirty (30) days after the Closing Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondents

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shall provide a copy of the notification to the relevant Acquirer. Respondents shall maintain complete records of all such notifications at the Respondents' registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications, and reminders sent to the Respondents' personnel.

M. Respondents shall:

1. for a period of twelve (12) months after the Closing Date, provide the Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and Divestiture Product Assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s);"
2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to the relevant Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer or Proposed Acquirer(s), provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by that Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, (ii) use the information solely in

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connection with considering whether to provide, or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use;

3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer, and remove any impediments within the control of a Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with a Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, a Respondent shall not make any counteroffer to any Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit a Respondent from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with a Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to

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research, Develop, manufacture, and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Business related to the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by a Respondent until the Closing Date(s) for the divestiture of the Divestiture Product Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that this Paragraph does not require nor shall be construed to require a Respondent to terminate the employment of any employee or to prevent a Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year after the Closing Date, not: (i) directly or indirectly solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or (ii) hire any Divestiture Product Employee;

provided, however, a Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with that Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that a Respondent may do the following: (i) advertise for employees in

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newspapers, trade publications, or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts a Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from that Respondent.

N. Until Respondents complete the divestitures required by this Order and fully provide, or causes to be provided, the Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer:

1. Respondents shall take actions as are necessary to:
 - a. maintain the full economic viability and marketability of the Businesses associated with that Divestiture Product;
 - b. minimize any risk of loss of competitive potential for that Business;
 - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;
 - d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product;
 - e. ensure the completeness of the transfer and delivery of the Manufacturing Technology; and
2. Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in this Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses related to that Divestiture Product.

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- O. Respondents shall not, in the United States of America:
1. use any of the Trademarks related to Divestiture Products or any mark confusingly similar to the Trademarks as a trademark, tradename, or service mark *except* as may be necessary to sell inventory of Divestiture Products in existence as of the Acquisition Date or as otherwise specifically permitted by the Acquirer of the relevant Divestiture Product;
 2. attempt to register the Trademarks;
 3. attempt to register any mark confusingly similar to the Trademarks;
 4. challenge or interfere with an Acquirer's use and registration of the Trademarks acquired by that Acquirer; or
 5. challenge or interfere with an Acquirer's efforts to enforce its trademark registrations for and trademark rights in the relevant Trademarks against Third Parties.
- P. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export,

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use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America.

- Q. For any patent infringement suit filed prior to the Closing Date in which a Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that a Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America, that Respondent shall:
1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;
 2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and
 3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work product in the possession of that Respondent's outside counsel related to that Divestiture Product.
- R. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related

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Manufacturing Technology and the related obligations imposed on the Respondents by this Order is:

1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the United States of America;
2. to create a viable and effective competitor that is independent of Respondents in the Business of each Divestiture Product within the United States of America; and
3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

III.

IT IS FURTHER ORDERED that:

- A. Edward J. Buthusiem shall serve as Monitor to assure that the Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets, and the Remedial Agreements.
- B. No later than one (1) day after the Acquisition Date, Respondents shall enter into the Monitor Agreement that is attached as Appendix V. and Non-Public Appendix V.A to the Order to Maintain Assets. The Monitor Agreement shall become effective on the date the Order to Maintain Assets is issued. Respondents shall transfer to and confer upon the Monitor all the rights and powers necessary to permit the Monitor to perform his duties and responsibilities in a manner consistent with the purposes of the Orders. Respondents shall assure, and the Monitor Agreement shall provide, that:

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1. The Monitor shall have the power and authority to monitor each Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
3. The Monitor shall serve until the latter of:
 - a. the date the Respondents complete the transfer of all Divestiture Product Assets, and the transfer and delivery of the related Manufacturing Technology, Product Intellectual Property, and Product Licensed Intellectual Property;
 - b. the date that each respective Acquirer has obtained all Product Approvals necessary to manufacture and market each Divestiture Product acquired by that Acquirer in the United States of America independently of the Respondents; or
 - c. the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture a Divestiture Product that is being monitored by the Monitor;

provided, however, that the Monitor's service shall not extend more than four (4) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

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- C. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to that Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that Respondent's compliance with the Orders.
- D. The Monitor shall serve, without bond or other security, at the expense of Respondent Integra, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent Integra, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- E. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.
- F. Respondents shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any

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reports submitted by the Acquirer with respect to the performance of a Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order; *provided, however*, beginning ninety (90) days after Respondents have filed its final report pursuant to Paragraph VII.C., and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by the Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.

- G. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- H. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- I. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- J. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.

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- K. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.**IT IS FURTHER ORDERED** that:

- A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the

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identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
 - 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
 - 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets

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that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of

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Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.

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8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
 9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by this Order.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, Respondents shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access

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original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. to assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

provided, however, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement, or arrangement;

provided further, however, that pursuant to this Paragraph, Respondents needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VI.

IT IS FURTHER ORDERED that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.

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- B. Any failure by Respondents to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.
- D. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of Respondents, all as soon as reasonably practicable.
- E. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- F. Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

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VII.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition Date, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition Date occurred.
- B. Within five (5) days of each Closing Date, Respondents shall submit to the Commission a letter certifying the date on which that particular divestiture occurred.
- C. Within thirty (30) days after the Order Date, and every ninety (90) days thereafter until Respondents have (i) transferred all of the Divestiture Assets to the relevant Acquirer(s); and (ii) fully provided the Manufacturing Technology, Product Intellectual Property, and Product Licensed Intellectual Property to the relevant Acquirers, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with these requirements of the Orders. Respondents shall submit at the same time a copy of its report concerning compliance with this Order to the Monitor, if any Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Orders, including:
 - 1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, and (ii) any transitional services being provided by Respondents to the relevant Acquirer; and
 - 2. a detailed description of the timing for the completion of such obligations.

Decision and Order

- D. One (1) year after the Order Date, annually for the next four (4) years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

VIII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B. any proposed acquisition, merger, or consolidation of a Respondent; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

IX.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to a Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that Respondents shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of

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the authorized representative(s) of the Commission and at the expense of that Respondent; and

- B. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that Respondent Johnson & Johnson's obligations under the Orders, other than the provisions regarding employment contained in Paragraph II of this Order, shall terminate on the date on which all of the following have occurred:

- A. the Transferred Assets are completely owned and controlled either by Integra or an Acquirer;
- B. with respect to any Divestiture Product or related Product Intellectual Property or Manufacturing Technology, that is owned or controlled by Johnson & Johnson prior to the Acquisition, Johnson & Johnson has:
 - 1. transferred all rights and assets that were owned or controlled by Johnson & Johnson prior to the Acquisition and necessary to effect the related divestitures to either Integra or the Acquirer;
 - 2. transferred or otherwise provided all rights, assets or other resources that were owned or controlled by Johnson & Johnson prior to the Acquisition and necessary for Integra to provide the technical services and assistance to the Acquirer; and
 - 3. secured all consents and waivers from all Third Parties that are necessary to divest the Divestiture Assets to an Acquirer or certified that the Acquirer has executed all such agreements directly with each of the relevant Third Parties;

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- C. with respect to any Product Licensed Intellectual Property, Johnson & Johnson has granted or otherwise provided the rights to use such intellectual property either directly to the Acquirer, or to Integra for the purposes of providing such rights to the Acquirer;
- D. Johnson & Johnson has completed its obligations as specified in the *Transition Manufacturing Services Agreement* and the *Transition Services Agreement* by and between Depuy Synthes, Inc. and Natus Medical Incorporated; and
- E. Johnson & Johnson certifies to the Commission that all of the above-described services, acquisitions and transfers have occurred and all of the above-described consents and waivers from Third Parties have been provided to the Acquirer.

XI.

IT IS FURTHER ORDERED that this Order shall terminate on December 21, 2027.

By the Commission.

**NON-PUBLIC APPENDIX I
ACQUISITION AGREEMENT**

[Cover Page]

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**NON-PUBLIC APPENDIX II
DIVESTITURE AGREEMENTS**

[Cover Page]

**NON-PUBLIC APPENDIX III
DIVESTITURE PRODUCTS**

[Cover Page]

**NON-PUBLIC APPENDIX III.A.
CEREBROSPINAL FLUID COLLECTION SYSTEMS**

[Cover Page]

**NON-PUBLIC APPENDIX III.B.
DURAL GRAFT PRODUCTS**

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**NON-PUBLIC APPENDIX III.C.
FIXED PRESSURE VALVE SHUNT SYSTEMS**

[Cover Page]

**NON-PUBLIC APPENDIX III.D.
INTRACRANIAL PRESSURE MONITORING SYSTEMS**

[Cover Page]

**NON-PUBLIC APPENDIX III.E.
NON-ANTIMICROBIAL EXTERNAL VENTRICULAR
DRAINAGE CATHETERS**

[Cover Page]

**NON-PUBLIC APPENDIX III.F.
FIXED PRESSURE VALVE SHUNT SYSTEMS
EQUIPMENT**

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APPENDIX IV
CRANIAL ACCESS KITS

Product Description	SKU
CRANIAL KIT - NO DRUGS	INS5HND
CRANIAL DRILL KIT 1/4"	INS7040
CRANIAL KIT WITH THREE DRILL BITS	INS7250
CRANIAL KIT WITH TWO DRILL BITS	INS7260
CRANIAL KIT WITH VARIABLE BITS	INS7270
CRANIAL KIT WITH 5.31MM BIT	INS7280
HITH KIT	INSHITH
INS5HND without ventricular needle and razor, and 31" x 51" drape	INSHITH ND
INSHITH with ventricular needle and razor, and 31" x 51" drape	INSHITH RZN

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**APPENDIX V
MONITOR AGREEMENT**

MONITOR AGREEMENT

THIS AGREEMENT is made on **September 12, 2017**

BETWEEN:

Integra LifeSciences Holdings Corporation, a Delaware corporation (“Integra”)

- and -

Johnson & Johnson, a New Jersey corporation (“Johnson & Johnson”)

- and -

Berkeley Research Group, LLC, a corporation governed by the laws of Nevada (“BRG”)

RECITALS:

- A. Integra and DePuy Synthes, Inc.—a Delaware corporation controlled by Johnson & Johnson—have entered into an Asset Purchase Agreement, dated as of February 14, 2017, pursuant to which Integra agrees to buy certain products for use in connection with neurosurgery procedures;
- B. Integra and Johnson & Johnson (collectively, “Respondents”) have entered—or will shortly enter—into an Agreement Containing Consent Order with the Commission (the “Consent Agreement”);
- C. The Consent Agreement requires Respondents to divest certain assets to Natus Medical Incorporated pursuant to, and in accordance with, certain divestiture agreements, and provides that Edward J. Buthusiem shall serve as a Monitor, to ensure that Respondents comply with their obligations under the Consent Agreement;
- D. BRG has consented to the appointment of Edward Buthusiem, a managing director of BRG’s Healthcare Analytics Practice, to act as the Monitor; and
- E. Respondents seek to transfer to BRG, and BRG agrees to assume, all rights and powers necessary to permit BRG to monitor Respondents’ compliance with the terms of the Consent Agreement.

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THEREFORE the Parties agree as follows:

I. DEFINITIONS

- [1] Whenever used in this Monitor Agreement, the following words and terms have the meanings set out below:
- (a) **"BRG"** means Berkeley Research Group, LLC, its directors, officers, agents, employees, representatives, successors and assigns;
 - (b) **"Commission"** means the Federal Trade Commission;
 - (c) **"Consent Agreement"** means Consent Agreement as defined in the recitals to this Monitor Agreement;
 - (d) **"Respondents"** means Integra and Johnson & Johnson;
 - (e) **"Monitor Agreement"** means this Monitor Agreement, including Schedule I hereto, and references to any "Section", "Part" or "Paragraph" shall, unless otherwise indicated, mean a section, part or paragraph of this Monitor Agreement;
 - (f) **"Integra"** means Integra LifeSciences Holdings Corporation; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Integra LifeSciences Holdings Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each;
 - (g) **"Johnson & Johnson"** means Johnson & Johnson's directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Johnson & Johnson (including, without limitation, Johnson & Johnson's Codman Neuro division and DePuy Synthes, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each; and
 - (h) **"Natus"** means Natus Medical Incorporated, a Delaware corporation
 - (i) **"Parties"** means Integra, Johnson & Johnson, and BRG collectively, and **"Party"** means any one of them.
- [2] Capitalized terms used and not specifically defined herein shall have the definitions given to them in the Consent Agreement.

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II. RIGHTS AND OBLIGATIONS OF THE PARTIES

- [3] This Monitor Agreement is entered into pursuant to the terms of the Consent Agreement. BRG shall have all of the rights, powers, duties, obligations, responsibilities and protections that are possessed by or apply to the Monitor under the Consent Agreement. In the event of any discrepancy between the rights, powers, duties, obligations, responsibilities and protections that are possessed by or apply to the Monitor as set out in the Monitor Agreement and the Consent Agreement, the Consent Agreement shall prevail. Without limiting the generality of the foregoing, Respondents hereby grant to BRG all rights and powers necessary to permit BRG to monitor Respondents' compliance with the Consent Agreement including Respondents' compliance with the Consent Agreement's requirement that Respondents preserve and maintain the Divestiture Products and Divestiture Product Businesses.
- [4] A reference in this Monitor Agreement to specific monitoring functions or tasks that are to be undertaken by BRG shall in no way detract from BRG's general right, power and duty to monitor all aspects of Respondents' compliance with the Consent Agreement.
- [5] Respondents and BRG consent to the following terms and conditions regarding BRG's rights, powers and duties:
 - (a) BRG shall have the power and authority to monitor each Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Consent Agreement, and any Remedial Agreement, including any Divestiture Agreement(s), and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Consent Agreement and in consultation with the Commission.
 - (b) BRG shall act in a fiduciary capacity for the benefit of the Commission, maintain all confidences and avoid any conflict of interest.
 - (c) BRG shall have the authority to employ, at the expense of Integra, such consultants, accountants, attorneys, and other representatives and assistants as BRG believes are reasonably necessary to carry out its duties and responsibilities.
 - (d) BRG shall have no obligation or authority to operate or maintain the Divestiture Products.
 - (e) BRG shall have no duties of good faith, of a fiduciary nature, or otherwise, to Respondents.
 - (f) Respondents shall report to BRG in accordance with the requirements of the Consent Agreement and as otherwise provided in any agreement

Decision and Order

approved by the Commission. BRG shall evaluate the reports submitted to BRG by a Respondent, and any reports submitted by the Acquirer with respect to the performance of a Respondent's obligations under the Consent Agreement or the Remedial Agreement(s). Within thirty (30) days after the date BRG receives these reports, BRG shall report in writing to the Commission concerning performance by Respondents of their obligations under the Consent Agreement; *provided, however*, beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph VII.C. of the Decision and Order, which is part of the Consent Agreement, and ninety (90) days thereafter, BRG shall report in writing to the Commission concerning progress by the Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents. BRG shall, within 3 Business Days, respond to any request by the Commission for additional information regarding any Respondent's compliance.

- [6] Subject to any demonstrated legally recognized privilege, BRG shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as BRG may reasonably request, related to that Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of BRG and shall take no action to interfere with or impede BRG's ability to monitor that Respondent's compliance with the Orders.
- [7] Respondents shall fully and promptly respond to all requests from BRG and shall provide all information BRG may request that is relevant to monitoring Respondents' compliance with the Consent Agreement. Each Respondent shall identify an individual who shall have primary responsibility for responding fully and promptly to such requests from BRG on behalf of that Respondent.
- [8] Respondents shall provide to BRG electronic or hard copies, as appropriate, of all reports submitted by Respondents to the Commission pursuant to the Consent Agreement, simultaneously with the submission of such reports to the Commission, for the duration of BRG's term under this Monitor Agreement.
- [9] Respondents and BRG shall be reasonably available to one another to discuss any questions or issues either Party may have concerning compliance with the Consent Agreement.
- [10] BRG shall report to the Commission in accordance with the terms of the Consent Agreement. Respondents acknowledge that BRG will not provide to Respondents copies of its reports to the Commission, nor will BRG provide to Respondents any information respecting BRG's dealings with the Commission.

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III. COMPENSATION

- [11] Integra shall be responsible for all reasonable fees and expenses properly charged or incurred by BRG in the course of carrying out BRG's duties under the Consent Agreement. BRG shall serve, without bond or security, on the terms set out in Schedule I to this Monitor Agreement, and shall account for all fees and expenses incurred. Integra shall pay all reasonable invoices submitted by BRG within 60 days after receipt and, without limiting this obligation, Integra shall comply with any agreement it reaches with BRG regarding interest on late payments. In the event of any dispute: (i) such invoice shall be subject to the approval of the Commission; and (ii) Integra shall promptly pay any invoice approved by the Commission. Any outstanding monies owed to BRG by Integra shall be paid out of the proceeds of the Divestiture.

IV. CONFIDENTIALITY

- [12] Respondents may require BRG and each of BRG's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict BRG from providing any information to the Commission.
- [13] The Commission may, among other things, require BRG and each of BRG's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of BRG's duties.
- [14] BRG shall maintain the confidentiality of all Confidential Business Information provided to BRG by Respondents or any Purchaser approved by the Commission pursuant to the Consent Agreement. Such information shall be used by BRG only in connection with the performance of BRG's duties pursuant to this Monitor Agreement. Such Confidential Business Information shall not be disclosed by BRG to any Third Party other than:
- (a) employees of BRG who have signed a confidentiality acknowledgement requiring them to abide by the confidentiality terms of this Monitor Agreement;
 - (b) consultants, attorneys or other representatives or assistants employed by BRG who have signed a confidentiality agreement requiring them to abide by the terms of this Monitor Agreement;
 - (c) the Commission and any Commission staff or counsel;
 - (d) the Divestiture Trustee; or
 - (e) other persons if consented to by Respondents and the Commission.

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- [15] BRG shall maintain a record of and inform the Commission of all Persons (other than representatives of the Commission) to whom Confidential Business Information related to this Monitor Agreement has been disclosed.
- [16] Upon termination of BRG's duties under this Monitor Agreement, BRG shall promptly (i) return to Respondents all Records provided to BRG by Respondents; and (ii) destroy any Records prepared by Respondents that contain or reflect any Confidential Business Information of Respondents. BRG shall make no use of any Confidential Business Information of Respondents, or any information derived directly or indirectly from any Confidential Business Information of Respondents, following termination of its duties. Nothing herein shall abrogate BRG's duty of confidentiality, including the obligation to keep any Confidential Business Information of Respondents confidential in perpetuity after the termination of this Monitor Agreement.
- [17] BRG shall keep confidential in perpetuity its reports to, and any other correspondence with, the Commission. BRG shall maintain the confidentiality, for a period of ten (10) years after the termination of this Monitor Agreement, of all other aspects of the performance of BRG's responsibilities under this Monitor Agreement and not disclose any Confidential Business Information relating thereto except as required by law. In the event that BRG is requested pursuant to subpoena or other legal process to produce any documents or to provide testimony relating to this matter in judicial or administrative proceedings to which BRG is not a party, Integra shall reimburse BRG at standard billing rates for all professional time and expenses, including reasonable attorney's fees, incurred in preparing for and responding to requests for documents and providing testimony.

V. INDEMNITIES AND RIGHTS OF ACTION

- [18] Respondents shall indemnify BRG and hold BRG harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection with, the performance of BRG's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defence of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by BRG. In addition, except to extent arising from BRG's gross negligence, willful or wanton acts, or bad faith, BRG shall not be liable to Respondents for any consequential, incidental, special or punitive damages and BRG shall not be liable to Respondents for direct compensatory damages in excess of the fees actually received by BRG for the performance of services hereunder.
- [19] BRG shall have no claim against the Commission arising out of the performance of BRG's duties under this Monitor Agreement or the Consent Agreement.

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VI. TERM AND TERMINATION

[20] BRG shall serve until the latter of:

- (i) the date the Respondents complete the transfer of all Divestiture Product Assets, and the transfer and delivery of the related Manufacturing Technology, Product Intellectual Property, and Product Licensed Intellectual Property;
- (ii) the date that each respective Acquirer has obtained all Product Approvals necessary to manufacture and market each Divestiture Product acquired by that Acquirer in the United States of America independently of the Respondents; or
- (iii) the date of written notification from staff of the Commission that BRG, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture a Divestiture Product that is being monitored by BRG;

provided, however, that BRG's service shall not extend more than four (4) years after the Order Date unless the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders or otherwise terminate the monitor's service.

[21] BRG may terminate this Agreement without penalty upon 30 days' notice to Respondents and to the Commission. In such instance, BRG shall provide reasonable support to the Commission, Respondents and to any substitute Monitor appointed in accordance with the Consent Agreement (the "Substitute Monitor") to facilitate the transition of BRG's monitoring role to the Substitute Monitor.

[22] Parts IV and V of this Monitor Agreement shall survive its termination.

[23] If, during the term of this Monitor Agreement, BRG becomes aware that BRG has or may have a conflict of interest that may affect or could have the appearance of affecting the performance by BRG of any of its duties under this Monitor Agreement, BRG shall immediately inform both Respondents and the Commission of such conflict or potential conflict.

[24] If the Commission determines that BRG has ceased to act or has failed to act diligently, the Commission may remove BRG and appoint a Substitute Monitor. The provisions of the Consent Agreement respecting the Monitor shall apply in the same manner to any Substitute Monitor.

[25] If the Commission advises BRG and Respondents that he has determined, in its sole discretion, that there is cause for removal of BRG and appointment of a Substitute Monitor, whether due to an actual or perceived conflict of interest or otherwise in accordance with the Consent Agreement, this Monitor Agreement

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shall immediately terminate without notice or penalty. Notwithstanding such termination, BRG shall provide reasonable support to the Commission, Respondents, and to any Substitute Monitor to facilitate the transition of BRG's monitoring role to the Substitute Monitor.

VII. GENERAL

- [26] In the event that there is a disagreement or dispute between Respondents and BRG concerning Respondents' obligations under the Consent Agreement, and such disagreement or dispute cannot be resolved by the Parties, either Party may seek the assistance of the Commission to resolve the dispute.
- [27] This Monitor Agreement shall be governed by and interpreted in accordance with the law of the state of New York without applying any otherwise applicable conflict of law rules.
- [28] It is understood that BRG will serve under this Monitor Agreement as an independent contractor and that the relationship of employer and employee shall not exist between BRG and Respondents.
- [29] This Agreement may be executed in two or more counterparts, each of which shall be an original instrument, but all of which shall constitute one and the same Agreement.
- [30] The Commission may on its own initiative, or at the request of BRG, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Consent Agreement.
- [31] The Monitor appointed pursuant to the Consent Agreement may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Consent Agreement.

VIII. NOTICES

- [32] The Parties shall rely on the procedures and addresses for giving notice contained in the Consent Agreement. Communications addressed to BRG shall be addressed to:

Edward Buthusiem
Berkeley Research Group, LLC
1800 M St. NW, Second Floor
Washington, DC 20036

Decision and Order

IN WITNESS OF WHICH the Parties have executed this Agreement.

DATED this 17th day of September, 2017

**INTEGRA LIFESCIENCES HOLDINGS
CORPORATION**

Name:

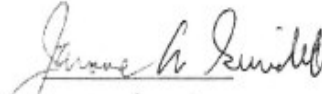


Title:

Corporate Vice President, General Counsel,
Administration & Secretary

JOHNSON & JOHNSON

Name:



Title:

Asst. Secretary

**BERKELEY RESEARCH
GROUP, LLC**

Name:



Title:

Managing Director

Analysis to Aid Public Comment

**NON-PUBLIC APPENDIX V.A
MONITOR AGREEMENT****ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT****INTRODUCTION**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Integra LifeSciences Holdings Corporation (“Integra”) and Johnson & Johnson designed to remedy the anticompetitive effects resulting from Integra’s proposed purchase of certain assets of Johnson & Johnson’s Codman Neuro (“Codman”) division. The proposed Decision and Order (“Order”) contained in the Consent Agreement requires the parties to divest all rights and assets to Natus Medical Incorporated (“Natus”) related to Integra’s intracranial pressure monitoring systems and fixed pressure valve shunt systems, as well as Codman’s cerebrospinal fluid collection systems, non-antimicrobial external ventricular drainage catheters, and dural grafts.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the Consent Agreement final.

Under the terms of the Asset Purchase Agreement signed on February 14, 2017, Integra will acquire Codman in a transaction valued at approximately \$1.0 billion (the “Acquisition”). The Commission’s Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially

Analysis to Aid Public Comment

lessening competition in the U.S. markets for intracranial pressure monitoring systems, cerebrospinal fluid collection systems, non-antimicrobial external ventricular drainage catheters, fixed pressure valve shunt systems, and dural grafts. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in these markets as a result of the proposed Acquisition.

THE PARTIES

Integra, headquartered in Plainsboro, New Jersey, is a medical device company with worldwide operations and one of the largest surgical instrument suppliers in the United States. The company has two U.S. business units: Specialty Surgical Solutions and Orthopedics and Tissue Technologies. The Specialty Surgical Solutions division offers instruments and systems for, among other specialties, neurosurgery and critical care.

Codman, part of Johnson & Johnson's DePuy Synthes Inc. business unit, is a global medical device company that offers a diverse portfolio of neurosurgery, neurovascular, and drug delivery products, including instruments and systems for hydrocephalus management, neurointensive care, and cranial surgery, as well as implantable drug infusion systems. The proposed transaction excludes Codman's neurovascular and drug delivery businesses.

THE RELEVANT PRODUCTS AND STRUCTURE OF THE MARKETS

I. Intracranial Pressure Monitoring Systems

Intracranial pressure monitoring systems are used in intensive care units and operating rooms to measure pressure inside the skull, which can increase in the event of traumatic brain injury, hydrocephalus, intracranial tumors, and other medical conditions. An increase in intracranial pressure can severely damage the brain or spinal cord and is a common cause of death in neurosurgical patients, making quick detection of pressure buildup critical. Intracranial pressure monitoring systems use a pressure-sensitive probe inserted through the skull to send measurements via a transducer cable to a monitor at the patient's bedside. Customers

Analysis to Aid Public Comment

would not switch to an alternative product in response to a small but significant increase in the price of intracranial pressure monitoring systems.

Integra and Codman are the only significant suppliers in the U.S. market for intracranial pressure monitoring systems, accounting for 68% and 26% of 2016 sales, respectively. The remainder of the market is comprised of small, fringe competitors that have limited competitive significance.

II. Cerebrospinal Fluid Collection Systems

Cerebrospinal fluid collection systems drain excess cerebrospinal fluid and monitor pressures within the fluid. They consist of a plastic drainage bag, tubing, and other accessories that connect to a patient through an external ventricular drainage catheter. There are no viable alternatives to cerebrospinal fluid collection systems.

Integra, Codman, and Medtronic are the only competitively significant suppliers of cerebrospinal fluid collection systems in the United States. Integra is the leading supplier with 57% of the market. Medtronic accounts for an additional 27% of the market, and Codman has a share of 14%. The next closest competitor is Möller Medical, which offers a more complex technology and only accounts for a nominal share of the market.

III. Non-Antimicrobial External Ventricular Drainage Catheters

External ventricular drainage catheters funnel excess cerebrospinal fluid from the brain to cerebrospinal fluid collection systems to relieve intracranial pressure. External ventricular drainage catheters are either antimicrobial or non-antimicrobial, and the two types constitute distinct antitrust markets because of the substantial differences between them. Non-antimicrobial external ventricular drainage catheters lack an antibiotic coating and are suitable for less critical patients; they also may be used to avoid the risk of antibiotic interference when diagnosing infections. They are significantly less expensive than antimicrobial external ventricular drainage catheters. Customers would not switch from non-antimicrobial external ventricular

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drainage catheters to the antimicrobial versions or any other product in response to a 5% to 10% increase in the price of non-antimicrobial external ventricular drainage catheters, in part because even with such a price increase, antimicrobial external ventricular drainage catheters would still be considerably more expensive.

Integra and Codman account for 29% and 17% of the relevant market in the United States. The only other competitively significant firm is Medtronic, with a 51% share.

IV. Fixed Pressure Valve Shunt Systems

Shunts are the primary tool that neurosurgeons use to treat hydrocephalus, or excessive accumulation of cerebrospinal fluid. Shunt systems redirect excess cerebrospinal fluid from the brain or spinal cord to another area of the body, usually the abdomen, for reabsorption. Shunt systems consist of three components: a ventricular catheter inserted into the brain, a valve to regulate the flow of the fluid, and another catheter that is threaded to the location where the fluid is emptied. Once implanted, the one-way valve in the shunt system regulates the pressure in the brain by governing the amount and pressure of cerebrospinal fluid passing through the catheter.

There are two main types of hydrocephalus shunts: fixed pressure valve shunts and programmable valve shunts. Fixed pressure valve shunts allow cerebrospinal fluid to pass through the shunt only when the pressure has exceeded some predetermined setting, which medical providers cannot adjust once implanted without another surgery. The settings on a programmable valve shunt system, which is significantly more expensive, can be adjusted non-invasively using specially designed magnetic tools. An insufficient number of customers are likely to switch to programmable valve shunts to prevent a small but significant increase in the price of fixed pressure valve shunt systems.

Integra, Codman, and Medtronic are the only significant suppliers of fixed pressure valve shunt systems. Medtronic accounts for 55% of U.S. sales, and Integra follows at 23% share and Codman at 15% share. Aesculap and Sophysa hold small,

Analysis to Aid Public Comment

fringe positions in the market and their products are not close substitutes to those of Integra and Codman.

V. Dural Grafts

Dural grafts are used to repair or replace a patient's dura mater, the thick membrane that surrounds the brain and spinal cord and keeps cerebrospinal fluid in place. Integra leads the U.S. market with 66% share of 2016 sales. In addition, Integra manufactures approximately 77% of the dural grafts sold in the United States. Medtronic, Codman, and Stryker account for 11%, 9%, and 8% of sales, respectively. Other suppliers account for only a nominal share of the market.

THE RELEVANT GEOGRAPHIC MARKET

The United States is the relevant geographic market in which to analyze the effects of the proposed Acquisition. These products are medical devices regulated by the U.S. Food and Drug Administration ("FDA"). Medical devices sold outside of the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

COMPETITIVE EFFECTS OF THE ACQUISITION

The proposed Acquisition would cause substantial competitive harm in the relevant markets. The parties are the only significant suppliers of intracranial pressure monitoring systems in the U.S. market, and two of only three significant suppliers of cerebrospinal fluid collection systems, non-antimicrobial external ventricular drainage catheters, and fixed pressure valve shunt systems in the United States. In the dural grafts market, a combined Integra/Codman would control the vast majority of the U.S. market and eliminate the close competition that exists between the parties today. Eliminating the head-to-head competition between Integra and Codman in all of these highly concentrated markets would allow the combined firm to exercise market power unilaterally, resulting in higher prices and reduced choice for customers in these markets.

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ENTRY CONDITIONS

Entry in the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. New entry would require significant investment of time and money to design and develop an effective product, obtain FDA approval, and develop clinical history supporting the long-term efficacy of a product. A new entrant must also establish a sales and marketing infrastructure, have or develop a track record of service and support, and offer a robust line of neurosurgical products sufficient to convince potential customers of the viability of its new product offerings. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market.

THE CONSENT AGREEMENT

The proposed Consent Agreement and Order remedy the competitive concerns raised by the proposed Acquisition by requiring the parties to divest to Natus all assets and rights to research, develop, manufacture, market, and sell Integra's intracranial pressure monitoring systems and fixed pressure valve shunt systems, as well as Codman's cerebrospinal fluid collection systems, non-antimicrobial external ventricular drainage catheters, and dural grafts. Integra is also required to divest its San Diego, California facility that manufactures a key component of its intracranial pressure monitoring systems. Additionally, to further ensure the divestitures are successful, the proposed Order requires the parties to supply Natus with cranial access kits for a limited time until Natus is able to secure supply of that product independently. The kit, which is often sold with the divestiture assets, includes items such as a hand drill, forceps, and sutures used during cranial surgery. The provisions of the Consent Agreement ensure that Natus becomes an independent, viable, and effective competitor in the respective U.S. markets in order to maintain the competition that currently exists.

Based in Pleasanton, California, Natus is a global healthcare company that provides screening, diagnostic, and monitoring solutions for its three business units: neurology, newborn care, and hearing and balance care. Its neurology business includes

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systems that are highly complementary to the divestiture assets and test for a variety of medical conditions, including epilepsy, head injury, tumors, Parkinson's, and sleep apnea. Natus is well positioned to restore the competition that otherwise would have been lost pursuant to the proposed Acquisition.

The parties must accomplish the divestitures and relinquish their rights to Natus no later than ten days after consummating the proposed Acquisition. If the Commission determines that Natus is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to Natus and then divest the products to a Commission-approved acquirer(s) within six months of the date the Order becomes final.

To ensure compliance with the Order, the Commission has agreed to appoint a Monitor to ensure that Integra and Johnson & Johnson comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to Natus. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

INTERLOCUTORY, MODIFYING,
VACATING, AND MISCELLANEOUS
ORDERS
