

Complaint

IN THE MATTER OF

**ABBOTT LABORATORIES
AND
ST. JUDE MEDICAL, INC.**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-4600; File No. 161 0126
Complaint, December 7, 2016 – Decision, February 14, 2017*

This consent order addresses the \$25 billion acquisition by Abbott Laboratories of certain assets of St. Jude Medical, Inc. 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 lessening competition in the U.S. markets for vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters. The consent order requires the parties are required to divest St. Jude’s vascular closure device business and Abbott’s steerable sheath business to Terumo Corporation.

Participants

For the *Commission*: Jordan S. Andrew and Sarah E. Wohl.

For the *Respondents*: George S. Cary and Tara Tavernia, Cleary Gottlieb Steen & Hamilton LLP; Bob Nichols and Joshua H. Soven, Gibson, Dunn & Crutcher 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 Abbott Laboratories (“Abbott”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Respondent St. Jude Medical, Inc. (“St. Jude”), 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

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public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Abbott is a corporation organized, existing and doing business under and by virtue of the laws of the State of Illinois, with its offices and principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064-6400.

2. Respondent St. Jude is a corporation organized, existing and doing business under and by virtue of the laws of the State of Minnesota, with its offices and principal place of business located at One St. Jude Medical Drive, St. Paul, Minnesota 55117.

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.

II. THE PROPOSED ACQUISITION

4. Pursuant to an Agreement and Plan of Merger dated April 27, 2016, Abbott proposes to acquire St. Jude in exchange for cash and stock valued at approximately \$25 billion (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKETS

5. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the development, licensing, manufacturing, marketing, distribution, and sale of the following medical devices:

- a. vascular closure devices;
- b. steerable sheaths; and
- c. lesion-assessing ablation catheters.

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6. For the purposes of this Complaint, the United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in the relevant lines of commerce.

IV. THE STRUCTURE OF THE MARKETS

7. Vascular closure devices are used to close arterial holes created by catheterization procedures, which are minimally-invasive processes during which a physician uses a specialized catheter to either diagnose or treat a cardiovascular condition. The U.S. market for vascular closure devices is highly concentrated with Abbott and St. Jude holding a combined 70 percent market share. Only two other suppliers, Cardinal Health, Inc. and Cardiva Medical, Inc., currently sell vascular closure devices in the United States.

8. Steerable sheaths are used to access difficult to reach areas of the heart to treat arrhythmias such as atrial fibrillation. Steerable sheaths allow physicians to more easily puncture the transseptal wall of the heart and guide an ablation catheter into the left atrium or ventricle of the heart. Currently, St. Jude accounts for the vast majority of steerable sheath sales in the United States. Abbott recently entered the U.S. market for steerable sheaths and appears well positioned to compete with St. Jude. Other suppliers in this market, though not recent entrants, have very small market shares.

9. Lesion-assessing ablation catheters are used to treat heart arrhythmias and provide feedback to the physician regarding the force being applied by the catheter or the temperature of the ablation target. St. Jude and Biosense Webster Inc. ("Biosense") are currently the only suppliers of lesion-assessing ablation catheters in the U.S. market. Advanced Cardiac Therapeutics, Inc. ("ACT") is developing lesion-assessing ablation catheter products that would compete directly with the lesion-assessing ablation catheters offered by St. Jude and Biosense in the United States. Abbott and ACT entered into a strategic partnership to develop lesion-assessing ablation catheters.

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V.EFFECTS OF THE ACQUISITION

10. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant market 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, in the following ways, among others:

- a. by eliminating actual competition between Abbott and St. Jude in the U.S. market for vascular closure devices;
- b. by eliminating actual competition between Abbott and St. Jude in the U.S. market for steerable sheaths;
- c. by eliminating potential competition between Abbott/ACT and St. Jude in the U.S. market for lesion-assessing ablation catheters if Abbott acquires ACT's lesion-assessing ablation catheter assets, thereby reducing additional competition that would have resulted from an additional U.S. supplier of lesion-assessing ablation catheters; and
- d. by increasing the ability of the merged entity to raise prices unilaterally in the relevant markets.

VI.ENTRY CONDITIONS

11. Entry into the relevant markets described in Paragraph 5 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 times and FDA approval requirements are lengthy. Although a limited number of firms other than Respondents may begin competing in some relevant markets in the future, such entry would not be timely or sufficient to prevent the competitive harm likely to result from the Acquisition.

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VII. VIOLATIONS CHARGED

12. The Agreement and Plan of Merger described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

13. The Acquisition described in Paragraph 4, if consummated, would constitute a 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.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-seventh day of December, 2016 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 merger of Respondent Abbott Laboratories (“Abbott”) and Respondent St. Jude Medical, Inc. (“St. Jude”), hereinafter 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

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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 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, this Order the Maintain Assets and makes the following jurisdictional findings:

1. Respondent Abbott Laboratories is a corporation organized, existing and doing business under and by virtue of the laws of the State of Illinois, with its offices and principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064-6400.
2. Respondent St. Jude is a corporation organized, existing and doing business under and by virtue of the laws of the State of Minnesota, with its offices and principal place of business located at One St. Jude Medical Drive, St. Paul, Minnesota 55117.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

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. "Abbott" means Abbott Laboratories, its directors, officers, employees, agents, and representatives; its

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successors and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Abbott, and the respective directors, officers, employees, agents, representatives, successors and assigns of each. After the Acquisition, Abbott will include St. Jude.

- B. “St. Jude” means St. Jude Medical, Inc., its directors, officers, employees, agents, and representatives; its successors and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by St. Jude, and the respective directors, officers, employees, agents, representatives, successors and assigns of each.
- C. “Respondent(s)” means Abbott and St. Jude, individually and collectively.
- D. “Commission” means the Federal Trade Commission.
- 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 the issuance and service of a final Decision and Order by the Commission in this matter.
- F. “Divestiture Product Business(es)” means the worldwide Businesses of Respondents related to each of the Assets To Be Divested to the extent that each such Business is owned, controlled, or managed by the Respondents and the assets related to such Businesses to the extent such assets are owned by, controlled by, managed by or licensed to, the Respondents.
- 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 Business, 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 Respondents to cease the marketing, distribution, and sale of Products related to the relevant Divestiture Product Business; (ii) the date on which the relevant Acquirer commences the marketing, distribution, and sale of all of the Products related to the relevant Divestiture Product Business in a manner that is fully independent of the Respondents; or four (4) months after the Closing Date for such Divestiture Product Business.
- 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 Assets To Be Divested to an Acquirer, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of the Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal or wasting, deterioration, or impairment of the Assets To Be Divested except for ordinary wear and tear. Respondents shall not sell, transfer, encumber or otherwise impair the Assets To Be Divested (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 Divestiture Product Businesses.
- B. Until Respondents fully transfer and deliver each of the respective Assets To Be Divested to an Acquirer, Respondents shall maintain the operations of the

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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; customers, Agencies; employees; and others having business relationships with each of the respective Divestiture Product Businesses, in the ordinary course of business and in accordance with past practice. Respondents shall use their best efforts to keep the organization and properties of the Divestiture Product Businesses intact, including current business operations, physical facilities and working conditions, and a work force of equivalent size, training, and expertise associated with the 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 Product Businesses and/or to prevent any diminution in sales of each of the Divestiture

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Product Businesses during and after the Acquisition process and prior to the complete transfer and delivery of the related Assets To Be Divested to an Acquirer;

4. 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
 5. Providing such support services to each of the respective Divestiture Product Businesses as were being provided to such Divestiture Product Business(es) by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Until Respondents fully transfer and deliver each of the respective Assets To Be Divested 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 Product Businesses for the relevant Assets To Be Divested's last fiscal year.
- D. During the Transition Period, 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 the Products related to each of the Divestiture Product Businesses by the Acquirer(s) is not delayed or impaired by the Respondents;
 2. Designate employees of Respondents knowledgeable about the marketing, distribution, and sale of the Products related to each of the

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Divestiture Product Businesses who will be responsible for communicating directly with the Acquirer(s), and the Monitor (if one has been appointed), for the purposes of assisting in the transfer of the Assets To Be Divested to the Acquirer(s);

3. Maintain and manage inventory levels of the Products of the Divestiture Product Businesses in consideration of the marketing and distribution transition to the Acquirer;
4. Continue to market, distribute, and sell the Products of the Divestiture Product Businesses;
5. Allow the Acquirer access at reasonable business hours to all Confidential Business Information related to the Divestiture Product Businesses 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 Product Businesses that contain such Confidential Business Information pending the completed delivery of such Confidential Business Information to the Acquirer;
6. Provide the Acquirer with a listing of inventory levels (weeks of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler, or distributor) on a regular basis and in a timely manner;
7. Provide the Acquirer with anticipated reorder dates for each customer 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.

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- E. Until Respondents fully transfer and deliver each of the respective Assets To Be Divested to an Acquirer, Respondents shall:
1. Not use, directly or indirectly, any Confidential Business Information related to the Assets To Be Divested other than as necessary to comply with the following:
 - a. The requirements of this Order;
 - b. Respondents' obligations to the Acquirer(s) 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(s), (ii) other Persons specifically authorized by such Acquirer(s) to receive such information (*e.g.*, employees of the Respondents responsible for the manufacture and/or supply of any Products or components related to the Assets to Be Divested on behalf of an Acquirer), (iii) the Commission, or (iv) the Monitor (if one has been appointed);
 3. Not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Products related to the Assets To Be Divested to the employees associated with Respondents' Retained Business(es) who are related to the marketing or sales of Respondents' Products identified in the Commission's Complaint as competing Products; and
 4. Institute procedures and requirements to ensure that the above-described employees:

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- 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.
- F. 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 Assets To Be Divested by Respondents' personnel to all of their employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information.
- G. 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 Respondents' registered offices within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgment program. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications, and reminders sent to Respondents' personnel.
- H. Respondents shall monitor the implementation by their 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

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acknowledgments required by this Order to Maintain Assets.

- I. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses through their full transfer and delivery to an Acquirer(s); to minimize any risk of loss of competitive potential for the Divestiture Product Businesses; and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Assets To Be Divested except for ordinary wear and tear.

III.

IT IS FURTHER ORDERED that:

- F. Edward J. Buthusiem shall serve as Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreement, including any Transition Services Agreement and Transitional Manufacturing and Supply Agreement, approved by the Commission.
- G. No later than one (1) day after the Acquisition Date, Respondents shall enter into the Monitor Agreement that is attached as Appendix II and Confidential Appendix II-1 to this Order to Maintain Assets. The Monitor Agreement shall become effective on the date this Order to Maintain Assets is issued. Respondents shall transfer to and confer upon the Monitor all the rights, powers, and authorities 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 responsibility and the power and authority to monitor Respondents' compliance with the terms of the Orders and the

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Remedial Agreement, including any Transition Services Agreement and Transitional Manufacturing and Supply Agreement, 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, in consultation with the Commission or its staff, including any directive from the Commission to the Respondents to effect such modifications to the manner of divestiture of the Assets to be Divested as are necessary to satisfy the requirements of this Order;

2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
3. The Monitor shall serve for such time as is necessary to monitor Respondents' compliance with the provisions of the Orders and the Remedial Agreement, including for as long as Respondents are providing Transition Services to the Acquirer pursuant to the Transition Services Agreement or supplying VCD Products or VCD Components to the Acquirer pursuant to the Transitional Manufacturing and Supply Agreement; *provided, however,* that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders;
4. 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 Respondents' compliance with its obligations under the Orders and the Remedial Agreement. 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

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Respondents' compliance with the Orders and the Remedial Agreement;

5. 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;
 6. 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; and
 7. 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 Respondents, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under this Order or the Remedial Agreement. 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 Orders.
- H. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and

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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.

- I. 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.
- J. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld, as follows: (a) If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor; and (b) not later than ten (10) days after appointment of a substitute Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondents' compliance with the terms of the Orders and the Remedial Agreement.
- K. 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 or the Remedial Agreement.
- 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.

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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 and the Paragraphs that are enumerated in Paragraph VII.C. of the related Decision and Order, 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 at the same time submit to the Monitor, if any Monitor has been appointed, a copy of their report concerning compliance with the Orders. Respondents shall include in their reports, among other things that are required from time to time, a detailed description of their 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 Respondent to the relevant Acquirer; and
- B. a detailed description of the timing for the completion of such obligations;

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 at the same time as, the reports required to be submitted by Respondents pursuant to Paragraph VII of 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;

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

VI.

IT IS FURTHER ORDERED that, for the purpose 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, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during office hours of the 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 Respondents relating to compliance with this Order, which copying services shall be provided by Respondents at their expense; and
- B. To interview officers, directors, or employees of the 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; or

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- B. The day after the divestiture of all of the Assets To Be Divested, as required by and described in the Decision and Order, has been completed; or
- C. The day after Respondents, with the concurrence of the Acquirer(s), certify in writing to the Commission as to the completion of all Transition Services provided by Respondents to the Acquirer(s) pursuant to any Transition Services Agreement, and of the manufacture and supply of any Products or components by the Respondents to the Acquirer(s) pursuant to any Transitional Manufacturing and Supply Agreement, in each instance pursuant to the Remedial Agreement approved by the Commission; or
- D. The day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Abbott Laboratories (“Abbott”) of Respondent St. Jude Medical, Inc. (“St. Jude”), hereinafter 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

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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”):

1. Respondent Abbott Laboratories is a corporation organized, existing and doing business under and by virtue of the laws of the State of Illinois, with its offices and principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064-6400.
2. Respondent St. Jude Medical, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Minnesota, with its offices and principal place of business located at One St. Jude Medical Drive, St. Paul, Minnesota 55117.
3. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and over Respondents, and the proceeding is in the public interest.

Decision and Order

I.

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

- A. “Abbott” means Abbott Laboratories, its directors, officers, employees, agents, and representatives; its successors and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Abbott, and the respective directors, officers, employees, agents, representatives, successors and assigns of each. After the Acquisition, Abbott will include St. Jude.
- B. “St. Jude” means St. Jude Medical, Inc., its directors, officers, employees, agents, and representatives; its successors and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by St. Jude, and the respective directors, officers, employees, agents, representatives, successors and assigns of each. St. Jude does not include Abbott.
- C. “Respondent(s)” means Abbott and St. Jude, individually and collectively.
- D. “Commission” means the Federal Trade Commission.
- E. “Acquirer” means the following:
 - 1. Terumo, if approved by the Commission; or
 - 2. Any other Person approved by the Commission to acquire the Assets to Be Divested pursuant to this Order.

Provided, however, that, if Terumo is not approved by the Commission as the Acquirer, the VCD Assets To Be Divested and the Steerable Sheath Assets To Be Divested may, in the Commission’s sole discretion, be divested to two different Acquirers that receive the prior approval of the Commission.

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- F. “Acquisition” means Abbott’s acquisition of St. Jude through a series of transactions as contemplated by and pursuant to the Agreement and Plan of Merger dated April 27, 2016, among Abbott Laboratories, St. Jude Medical, Inc., Vault Merger Sub, Inc., and Vault Merger Sub LLC that was submitted by the Respondents to the Commission.
- G. “Acquisition Date” means the date on which the Acquisition is consummated.
- H. “ACT” means Advanced Cardiac Therapeutics, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 22880 Lakeside Drive, Suite 250, Santa Clara, CA 95054.
- I. “Agency(ies)” means any governmental 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 Vascular Closure Devices or Steerable Sheaths. The term “Agency” includes, but is not limited to, the United States Food and Drug Administration (“FDA”).
- J. “Application(s)” means all submissions and applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Parts 800 to 898, including all premarket notifications (Section 510(k) submissions) and premarket approvals (“PMA”), and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.
- K. “Assets To Be Divested” means the VCD Assets To Be Divested and the Steerable Sheath Assets To Be Divested.

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- L. “Business” means the research, development, manufacture, commercialization, distribution, marketing, promotion, importation, exportation, advertisement, and/or sale of a Product.
- M. “Business Records” means all books, records, files, databases, printouts, and all other documents of any kind, whether stored or maintained in hard copy paper format, by means of electronic, optical, or magnetic media or devices, photographic or video images, or any other format or media, including, without limitation: customer files, customer lists, customer purchasing histories, supplier and vendor files, vendor lists, correspondence, advertising and marketing materials, marketing analyses, sales materials, price lists, cost information, employee lists and contracts, salary and benefits information, personnel files, financial and accounting records and documents, financial statements, financial plans and forecasts, operating plans, studies, reports, regulatory materials, Applications, Agency filings and submissions, Agency correspondence, operating guides, technical information, manuals, policies and procedures, service and warranty records, maintenance logs, equipment logs, registrations, and permits.
- N. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- O. “Closing Date(s)” means the date(s) on which Respondents (or a Divestiture Trustee) consummate a transaction to divest any of the Assets To Be Divested to an Acquirer(s) pursuant to this Order.
- P. “Confidential Business Information” means all information owned by, or in the possession or control of, Respondents that is not in the public domain and to the extent that it is directly related to the conduct of the VCD Business or the Steerable Sheath Business. The

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term “Confidential Business Information” excludes the following:

- a. Information relating to the Respondents’ general business strategies or practices that does not discuss the VCD Products or the Steerable Sheath Products with particularity;
- b. Information that is contained in documents, records, or books of the Respondents that are provided to an Acquirer by the Respondents that is unrelated to the VCD Products or the Steerable Sheath Products or that is exclusively related to the Retained Product(s); and
- c. 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.

Q. “Contracts” means all real and personal property leases, software licenses, Intellectual Property licenses, warranties, guaranties, insurance agreements, employment contracts, all contracts of any kind relating to construction, customer contracts, sales contracts, distribution contracts, supply agreements, utility contracts, collective bargaining agreements, confidentiality agreements, non-disclosure agreements, and other contracts or agreements of any kind.

R. “Copyrights” means rights to all original works of authorship of any kind directly related to a Product and any registrations and applications for registrations thereof, and all copyrightable works, registered and unregistered copyrights in both published works and unpublished works, and all applications, registrations, and renewals in connection therewith, including, but not limited to, the following: all such rights with respect to all promotional materials and all educational materials; copyrights in all preclinical, clinical, and process development data and reports relating to the

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research and development of any Product or of any materials used in the research, development, manufacture, marketing, or sale of any Product, including all copyrights in raw data relating to the clinical trials with respect to 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 customer information, promotional, and marketing materials; all Product sales forecasting models, medical education materials, sales training materials, and advertising and display materials; 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 any Product; 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.

- S. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent such costs are directly incurred to provide the relevant Product(s), inputs, components, goods, assistance or services. “Direct Cost” to the Acquirer(s) for its use of any of Respondents’ employees’ labor shall not exceed the average hourly wage rate for such employee;

Provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order; and (ii) an

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agreement becomes a Remedial Agreement for the Assets to be Divested, “Direct Cost” means such cost as is provided in such Remedial Agreement.

- T. “Divestiture Trustee” means any Person appointed by the Commission pursuant to Paragraph IV of this Order.
- U. “Employee(s)” means:
1. If Terumo is approved by the Commission to be the Acquirer, the employees identified in the Terumo Purchase Agreement; or
 2. If the Acquirer(s) is not Terumo, any individual employed on a full-time, part-time, or contract basis as of, and at any time after, April 28, 2016, the date of the announcement of the Acquisition, by:
 - a. St. Jude, where such employee’s job responsibilities relate or related primarily to the VCD Business; and
 - b. Abbott (or Kalila), where such employee’s job responsibilities relate or related primarily to the Steerable Sheath Business.
- V. “Facility Assets” means all of Respondents’ rights, title, and interests in and to the following:
1. All real property interests, including all rights, title, and interests in and to owned or leased property, together with all easements, rights of way, buildings, improvements, and appurtenances (“Facility(ies)”);
 2. All applicable federal, state, and local regulatory registrations, permits, and applications, and all documents related thereto, necessary for the operation and conduct of the Relevant Business at such Facility(ies) to the extent held by

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Respondents and with respect to which the transfer thereof is permitted by law; *provided, however*, that Respondents shall cooperate with the Acquirer in securing any federal, state, and local regulatory registrations, permits, and applications for which transfer is not permitted by law; and

3. All fixtures, equipment, machinery, tools, molds, dies, vehicles, personal property, or tangible property of any kind located at such Facility(ies) that are owned or leased by Respondents, or that Respondents have the legal right to use, or over which they have custody or control, that are related to:
 - a. The research, development, production, manufacture, marketing, or sale of any Product related to the Relevant Business; or
 - b. Compliance with any statute, ordinance, regulation, rule, or other legal requirement (including, but not limited to, environmental laws) of any Government Entity.
- W. “Governmental Entity” means any federal, state, local or non-U.S. government or any court, legislature, governmental Agency or governmental commission or any judicial or regulatory authority of any government.
- X. “Intellectual Property” means all intellectual property related to the Product(s) that is owned, licensed, or controlled by the Respondents as of the Closing Date, and all associated rights thereto, including all of the following in any jurisdiction throughout the world: (i) all Patents; (ii) all Trade Secrets; (iii) all Know-How; (iv) all Trademarks; (v) all Trade Dress; (vi) all Copyrights; (vii) all computer software (including source code, executable code, data, databases, and related documentation); (viii) all Marketing Materials; and (ix) all rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to sue and recover damages or obtain injunctive

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relief for infringement, dilution, misappropriation, misuse, violation, or breach of any of the foregoing.

- Y. “Inventories” means:
- a. All inventories, stores, and supplies of any semi-finished and finished Product(s) and work in progress; and
 - b. All inventories, stores, and supplies of raw materials and other materials relating to the research, development, manufacture, finishing, packaging, labeling, distribution, marketing, or sale of any Product(s).
- Z. “Kalila” means Kalila Medical, Inc., a Delaware corporation engaged in the Business of Steerable Sheath Products. Abbott acquired Kalila pursuant to the Kalila Acquisition.
- AA. “Kalila Acquisition” means the acquisition of Kalila by Abbott pursuant to the Agreement and Plan of Merger, dated January 29, 2016, by and among Abbott Laboratories, Topera, Inc., Kalila Medical, Inc., Kentucky Merger Sub, Inc., Shifamed, LLC and Shareholder Representative Services LLC; and the Paying Agent Agreement, dated January 29, 2016.
- BB. “Know-How” means know-how (including, but not limited to, flow sheets, process, and instrumentation), diagrams, risk analysis, certificates of analysis, goodwill, technology (including, but not limited to, equipment specifications), drawings, utility models, designs, design rights, techniques, data, inventions, practices, recipes, raw material specifications, and process descriptions).
- CC. “Law” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law by any Governmental Entity.

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- DD. “Manufacturing Technology and Equipment” means all technology and equipment to make a Product, including, but not limited to:
1. All technology, Trade Secrets, Know-How, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of a Product, including, but not limited to, all of the following: product specifications; processes; analytical methods; product designs; plans; ideas; concepts; manufacturing, engineering, and other manuals and drawings; standard operating procedures; flow diagrams; quality assurance and quality control systems; research records; clinical data; compositions; annual product reviews; regulatory communications; control history; current and historical information associated with FDA Application(s) conformance and cGMP compliance; labeling and all other information related to the manufacturing process; and supplier lists;
 2. All ingredients, materials, or components used in the manufacture of a Product; and
 3. All machinery, equipment, mechanical and spare parts, supplies, tools, tooling, jigs, molds, dies, production supplies, samples, media, and fixtures used to manufacture, finish, and package a Product (“Manufacturing Equipment”).
- EE. “Marketing Materials” means all materials used in the marketing or sale of a Product as of the Closing Date, including, without limitation, all advertising and display materials, promotional and marketing materials, training materials, educational materials, speaker lists, 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 used for marketing and sales

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research), customer information, sales forecasting models, website content, domain names (universal resource locators) and registrations thereof, artwork for the production of packaging components, and other materials related to the marketing or sale of a Product).

- FF. “Minnesota Facility” means Respondents’ Product manufacturing facility located at 14900 Minnetonka Industrial Road, Minnetonka, MN 55345, as specified in the Manufacturing and Supply Agreement between St. Jude and Terumo, which will be executed and become effective on the Closing Date, submitted as part of the Terumo Purchase Agreement.
- GG. “Monitor” means any Person appointed by the Commission pursuant to Paragraph III of this Order.
- HH. “Orders” means this Order and the Order to Maintain Assets.
- II. “Patents” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention, applications for certificates of invention, and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date, and includes all reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, substitutions, reexaminations, restorations, and/or patent term extensions thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all rights to obtain and file for patents and registrations thereto.
- JJ. “Person” means any individual, partnership, joint venture, firm, corporation, limited liability company, limited liability partnership, joint stock company, trust, unincorporated association or organization, or other business entity.
- KK. “Product(s)” means any medical device or system regulated by the FDA as a Class II (Special Controls)

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or Class III (PMA) medical device pursuant to 21 C.F.R. Parts 800 to 898, *i.e.*, an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, which is:

- a. recognized in the official National Foundry, or the United States Pharmacopoeia, or any supplement to them;
- b. 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
- c. 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.

LL. “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, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any Application related to that Product.

MM. “Proposed Acquirer” means any proposed acquirer of the Assets to Be Divested that Respondents or the Divestiture Trustee intend to submit or have submitted to the Commission for its approval under this Order. “Proposed Acquirer” includes Terumo.

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- NN. “Puerto Rico Facility” means Building B of the premises located at Zona Industrial Oeste Lot 20, Calle B, Caguas, Puerto Rico.
- OO. “Relevant Business” means the VCD Business or the Steerable Sheath Business.
- PP. “Remedial Agreement” means the following:
1. the Terumo Purchase Agreement, if approved by the Commission; and
 2. any other agreement between Respondent(s) and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has received the prior approval of the Commission to accomplish the requirements of this Order, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Assets To Be Divested, that have been approved by the Commission to accomplish the requirements of this Order.
- QQ. “Retained Business” means:
1. All assets, tangible or intangible, businesses, and goodwill related to all of the Retained Products of Respondents, including, but not limited to, all rights, title, and interest in and to all Intellectual Property, including the name “St. Jude Medical” or “Abbott Laboratories” together with all variations thereof and all Trademarks and Trade Dress containing, incorporating, or associated with any of the foregoing, and any Trademark and Trade Dress related thereto; and
 2. Cash and cash equivalents except cash and cash equivalents of Kalila; accounts receivable arising prior to the Closing Date; compensation or benefit plans except plans sponsored by Kalila; and tax assets.

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- RR. “Retained Product(s)” means any product researched, developed, manufactured, marketed, promoted, sold, or distributed by Respondents prior to the Acquisition other than the VCD Products and the Steerable Sheath Products.
- SS. “Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and clinical trial materials and information.
- TT. “Specified VCD Manufacturing Equipment” means all machinery, equipment, mechanical and spare parts, supplies, tools, tooling, jigs, molds, dies, production supplies, samples, media, and fixtures located at the Minnesota Facility that are exclusively related to the manufacture of the VCD Products produced at the Minnesota Facility.
- UU. “Steerable Sheath” means a medical device used to deliver tools, primarily diagnostic and therapeutic catheters, to the heart.
- VV. “Steerable Sheath Assets To Be Divested” means all of Abbott’s rights, title, and interests in and to all tangible and intangible assets and property of any kind used for or relating to the Steerable Sheath Business, wherever located, and all improvements or additions thereto, and as maintained by the Respondents in accordance with the Order to Maintain Assets until the Closing Date, including, without limitation, all of the issued and outstanding shares of capital stock acquired in the Kalila Acquisition, and the following:
1. All Intellectual Property;
 2. All Manufacturing Technology and Equipment;
 3. All Scientific and Regulatory Material;
 4. All Applications and rights to Applications;

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5. All Product Approvals;
6. All Marketing Materials;
7. All Contracts;
8. All Facility Assets;
9. All Inventories; and
10. All Business Records relating to the foregoing;

Provided, however, that:

- a. “Steerable Sheath Assets To Be Divested” do not include (1) the Retained Products or the Retained Business(es); and (2) any part of the Steerable Sheath Assets To Be Divested if not needed by an Acquirer and the Commission approves the divestiture without such assets;
- b. “Intellectual Property” does not include: (i) the corporate names or corporate Trade Dress of Respondents or the related corporate logos thereof, or the corporate names or corporate Trade Dress of any other corporations or companies owned or controlled by the Respondents or the related corporate logos thereof, or general registered images or symbols by which Respondents can be identified or defined; or (ii) the business marks specified on Schedule 5.07(a) of the Terumo Purchase Agreement; and
- c. Where Respondents’ Business Records contain information: (i) that relates both to the Assets To Be Divested and to Retained Products or the Retained Business(es) and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Assets To Be Divested; or (ii) for which the Respondents have a legal obligation to retain

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the original copies, Respondents shall be required to provide access or copies or relevant excerpts of the relevant Business Records containing this information. In instances where such copies are provided to the Acquirer, Respondents shall provide the Acquirer with 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 the Respondents completely to divest information that, in content, also relates to Respondents' Retained Products or Retained Business(es). Respondents shall also be permitted to retain copies of Business Records relating to the Assets To Be Divested to the extent necessary or required for the purposes of any ongoing legal proceedings, litigation, disputes, investigations, inquiries, subpoenas, reviews, audits or regulatory proceedings; *provided, however,* that Respondents shall comply with the requirements of Paragraph II.E. of this Order with respect to any Confidential Business Information contained in such copies of Business Records.

- WW. "Steerable Sheath Business" means the Business of Abbott relating to the Steerable Sheath Products acquired in the Kalila Acquisition, as conducted and maintained by Abbott since the Kalila Acquisition, including without limitation all improvements and activities relating thereto as of the Closing Date.
- XX. "Steerable Sheath Products" means the Steerable Sheaths and any related Products acquired by Abbott in the Kalila Acquisition, including all Products marketed or sold under the following Trademarks: Vado® 1.0, Vado® 1.1, and Vado® 2.1.

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- YY. “Terumo” means Terumo Corporation, a corporation organized, existing and doing business under and by virtue of the laws of Japan with its offices and principal place of business located at Tokyo Opera City Tower 50F; 3-20-2 Nishi-Shinjuku, Shinjuku-ku, Tokyo, 163-1450 Japan.
- ZZ. “Terumo Purchase Agreement” means the Purchase Agreement by and between Respondents and Terumo dated December 6, 2016, and the letter agreement with modifications dated January 5, 2017, and all amendments, exhibits, attachments, agreements, and schedules thereto, including, but not limited to: Transition Services Agreement by and between Respondent Abbott and Terumo, the Manufacturing and Supply Agreement between Respondent St. Jude and Terumo, and Quality Agreement between Respondent St. Jude and Terumo, each of which will be executed and become effective on the Closing Date, that have been approved by the Commission to accomplish the requirements of this Order. The Terumo Purchase Agreement is attached to this Order as Confidential Appendix I. The January 5, 2017, letter agreement with modifications is attached to this Order as Confidential Appendix I-I.
- AAA. “Third Party(ies)” means any Person other than the following: (1) the Respondents, or (2) the Acquirer.
- BBB. “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.
- CCC. “Trade Secret(s)” means all trade secrets, Know-How, and confidential or proprietary information, including ideas, research and development, formulas, compositions, technical data and information, blue prints, designs, drawings, specifications, protocols, quality control information, customer and supplier lists, pricing and cost information, business and

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marketing plans and proposals, and all other data, technology, and plans.

- DDD. “Trademark(s)” means all proprietary names or designations, registered and unregistered trademarks, service marks, trade names, brand names, commercial names, “doing business as” (d/b/a) names, logos, and slogans, together with all translations, adaptations, derivations, and combinations thereof, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof), all common law rights, and all goodwill symbolized thereby and associated therewith.
- EEE. “Transition Services” means technical services, personnel, assistance, training, and other logistical, administrative and transitional support as required by the Acquirer and approved by the Commission to facilitate the transfer of the Assets To Be Divested 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, R&D support, technology transfer, regulatory compliance, sales and marketing, customer service, and supply chain management and customer transfer logistics.
- FFF. “Transition Services Agreement(s)” means any agreement(s) that receives the prior approval of the Commission between the Respondents and the 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 Assets To Be Divested to the Acquirer in a manner consistent with the purposes of this Order.
- GGG. “Transitional Manufacturing and Supply Agreement(s)” means any agreement(s) that receives

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the prior approval of the Commission between the Respondents and the Acquirer to provide, at the option of the Acquirer, sufficient quantities of VCD Products and VCD Components for a period of time sufficient to allow the Acquirer to obtain all of the relevant Product Approvals necessary to manufacture the VCD Products and VCD Components in commercial quantities, and in a manner consistent with cGMP, independently of Respondents, and to secure relevant Manufacturing Equipment and sources of supply of VCD Components from Persons other than the Respondents.

- HHH. “Vascular Closure Device” means a medical device used to seal arterial holes generally following catheterization procedures accessed through the femoral artery.
- III. “VCD Products” means Vascular Closure Devices composed of an absorbable collagen sponge and absorbable polymer anchor, each connected by a self-tightening suture, and any related Products or devices, researched, developed, manufactured, marketed, promoted, or sold by St. Jude prior to the Acquisition, including all VCD Products marketed or sold under the Trademark Angio-Seal™.
- JJJ. “VCD Assets To Be Divested” means all of St. Jude’s rights, title, and interests in and to all tangible and intangible assets and property of any kind used for or relating to the VCD Business, wherever located, and all improvements or additions thereto, and as maintained by Respondents in accordance with the Order to Maintain Assets until the Closing Date, including, without limitation, the following:
1. All Intellectual Property;
 2. All Manufacturing Technology and Equipment, including, at the Acquirer’s option, the Specified VCD Manufacturing Equipment; *provided, however,* that the Specified VCD Manufacturing

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Equipment may be divested to the Acquirer only after completion by Respondents of any Transitional Manufacturing and Supply Agreements using such equipment.

3. All Scientific and Regulatory Material;
4. All Applications and rights to Applications;
5. All Product Approvals;
6. All Marketing Materials;
7. The Puerto Rico Facility and all Facility Assets related thereto; *provided, however*, that this includes only the portion of the lease agreement between Respondents and the Puerto Rico Industrial Development Company applicable to the Puerto Rico Facility;
8. All Contracts related to the Puerto Rico Facility;
9. All Contracts related to the research, development, manufacture, marketing, sale, and distribution of VCD Products and VCD Components at the Minnesota Facility, in each case only to the extent they are related to, and only upon completion of Respondents' obligations under, any Transitional Manufacturing and Supply Agreement for the supply of VCD Products and VCD Components to the Acquirer;
10. All Inventories related to the Puerto Rico Facility;
and
11. All Business Records;

Provided, however, that:

- a. "VCD Assets To Be Divested" do not include (1) the Retained Products or the Retained Business(es); and (2) any part of the VCD

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Assets to Be Divested if not needed by an Acquirer and the Commission approves the divestiture without such assets;

- b. “Intellectual Property” does not include: (i) the corporate names or corporate Trade Dress of Respondents or the related corporate logos thereof, or the corporate names or corporate Trade Dress of any other corporations or companies owned or controlled by the Respondents or the related corporate logos thereof, or general registered images or symbols by which Respondents can be identified or defined; or (ii) the business marks specified on Schedule 5.07(a) of the Terumo Purchase Agreement; and
- c. Where Respondents’ Business Records contain information: (i) that relates both to the Assets to be Divested and to Retained Products or Retained Business(es) and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Assets to be Divested; or (ii) for which the Respondents have a legal obligation to retain the original copies, Respondents shall be required to provide only copies or relevant excerpts of, or access to, the relevant Business Records containing this information. In instances where such copies are provided to the Acquirer, Respondents shall provide the Acquirer with 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 the Respondents completely to divest information that, in content, also relates to Respondents’ Retained Products or Retained Business(es). Respondents shall also be permitted to retain

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copies of Business Records relating to the Assets to be Divested to the extent necessary or required for the purposes of any ongoing legal proceedings, litigation, disputes, investigations, inquiries, subpoenas, reviews, audits or regulatory proceedings; *provided, however*, that Respondents shall comply with the requirements of Paragraph II.E. of this Order with respect to any Confidential Business Information contained in such copies of Business Records.

KKK. “VCD Business” means the Business conducted by St. Jude as of the Acquisition Date, and as maintained by Respondents up to the Closing Date, with respect to the VCD Products.

LLL. “VCD Component(s)” means the components specified and described in the Manufacturing and Supply Agreement between St. Jude and Terumo at the Terumo Purchase Agreement, Exhibit C.

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

A. No later than forty five (45) days after the Acquisition Date, Respondents shall divest the VCD Assets To Be Divested and the Steerable Sheath Assets To Be Divested to Terumo, absolutely and in good faith, at no minimum price, pursuant to and in accordance with the Terumo Purchase Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Terumo or to reduce any obligations of Respondents under such agreement);

Provided, however, that if Respondents have divested the Assets To Be Divested to Terumo prior to the date this Order is issued and served as final, and if, at the time the Commission determines to issue and serve

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this Order as final, the Commission notifies Respondents that Terumo is not an acceptable purchaser of one or both of the Assets To Be Divested, then Respondents shall immediately rescind the transaction with Terumo, in whole or in part, as directed by the Commission, and shall divest the Assets To Be Divested within ninety (90) days from the date this Order is issued, absolutely and in good faith, at no minimum price to an Acquirer or acquirers that receive 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 Assets To Be Divested to Terumo prior to the date this Order is issued and served as final, and if, at the time the Commission determines to issue and serve this Order as final, 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 Assets to Be Divested to Terumo (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, Respondents shall:
1. Secure, at their sole expense, all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the Assets To Be Divested to the Acquirer(s), and to permit the Acquirer(s) to continue to operate the Businesses related to the Assets To Be Divested in a manner that will achieve the purposes of this Order; *provided, however,* that the Respondents may satisfy this requirement by certifying that the Acquirer(s) has executed agreements or entered into equivalent arrangements directly with the relevant Third Party(ies); and

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2. Secure the transfer from the Respondents to the Acquirer(s) of any licenses, approvals, permits, registrations, certificates, rights, or other authorizations from any Persons or Governmental Entity(ies) that are necessary to accomplish the divestiture and transfer of the Assets To Be Divested to the Acquirer(s), and for the continued operation of such assets by the Acquirer(s), in a manner that will achieve the purposes of this Order;

Provided, however, that in the event Respondents are unable to secure the transfer to the Acquirer(s) of, or the Acquirer is unable to obtain, any license(s), approval(s), permits(s), registration(s), certificate(s), right(s), or authorization(s) with respect to the VCD Assets To Be Divested in any of the “Specified Jurisdictions” identified in the Terumo Purchase Agreement prior to the Closing Date, then Respondents shall:

- a. Continue to use best efforts and provide such assistance as the Acquirer(s) may reasonably request in connection with obtaining such license, approval, permit, registration, certificate, right, or other authorization until notification from such Specified Jurisdiction that the Acquirer(s) has been approved and/or is acceptable; but
- b. If within one hundred twenty (120) days after the Acquisition Date, a Specified Jurisdiction notifies Respondents and/or the Acquirer(s) that the Acquirer(s) has not been approved and/or is not acceptable to such Specified Jurisdiction, then, with the agreement of the Acquirer(s), and subject to the prior approval of the Commission, Respondents shall substitute an alternative arrangement; or
- c. If, after one hundred twenty (120) days after the Acquisition Date, the Specified Jurisdiction

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has not determined that the Acquirer(s) is approved or acceptable then Respondents shall:

- (i) report to the Commission on the circumstances surrounding such Specified Jurisdiction's review of the Acquirer(s); and
- (ii) if and as directed by the Commission, submit a proposal for an alternative arrangement, with the agreement of the Acquirer(s), for the prior approval of the Commission.

- C. 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 (2) years from the Closing Date; *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 to extend the term of a Transition Services Agreement as provided in this Paragraph. 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 Assets To Be Divested to the Acquirer and enable the Acquirer to operate the Assets To Be Divested in a manner consistent with the purposes of this Order.
- D. Respondents shall, at the option of the Acquirer, and subject to the prior approval of the Commission, enter into a Transitional Manufacturing and Supply Agreement to supply the Acquirer with VCD Products and VCD Components for a period of (2) years from the Closing Date; *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

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request, Respondents shall file with the Commission any request for prior approval to extend the term of a Transitional Manufacturing and Supply Agreement as provided in this Paragraph for such period of time as will be sufficient to allow the Acquirer to obtain all of the relevant Product Approvals necessary to manufacture the VCD Products and VCD Components in commercial quantities, and in a manner consistent with cGMP, independently of Respondents, and to secure relevant Manufacturing Equipment and sources of supply of VCD Components from Persons other than the Respondents. The VCD Products and VCD Components supplied by Respondents to the Acquirer pursuant to such Transitional Manufacturing and Supply Agreement shall be at no greater than Respondents' Direct Costs.

E. Respondents shall:

1. Provide to the Acquirer(s) originals or copies of, or access to all Confidential Business Information;
2. Deliver or provide access to such Confidential Business Information as follows: (i) in good faith; (ii) in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and (iii) 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 Acquirer, provide the 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 related to the Assets To Be Divested;
4. Not use, directly or indirectly, any Confidential Business Information, other than as necessary to comply with the following: (i) the requirements of

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this Order; (ii) the Respondents' obligations to the Acquirer under the terms of any Remedial Agreement related to the Assets to be Divested; or (iii) applicable Law, including mandatory regulatory filings;

5. Not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer, (ii) other Persons specifically authorized by the Acquirer to receive such information, (iii) the Commission, and (iv) the Monitor, if any, and the Divestiture Trustee, if any; and
6. No later than thirty (30) days after the Closing Date, provide written notification of the restrictions on the use of the Confidential Business Information to all Respondents' employees who are involved in the manufacture, distribution, sale, or marketing of the Assets to be Divested or who may have or have access to Confidential Business Information ("Designated Employees"); 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 at least one (1) year after the Closing Date. Respondents shall provide a copy of such notification to the Acquirer. Respondents shall maintain complete records at its principal place of business regarding the provision of notification to Designated Employees and shall provide an officer's certification to the Commission stating that such notification program has been implemented and is being complied with. Respondents shall provide the Acquirer with copies of all certifications, notifications, and reminders sent to Designated Employees.

Provided, however, that this Paragraph II.E. shall not apply to Confidential Business Information:

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- a. That Respondents can demonstrate to the Commission that Respondents obtained other than in connection with the Acquisition;
- b. To the extent related to Retained Products or the Retained Business;
- c. That subsequently falls within the public domain through no violation of the Order or breach of confidentiality and non-disclosure agreement with respect to such information by Respondents;
- d. That is necessary to be exchanged in the course of consummating the Acquisition or the transactions under the Remedial Agreement; and
- e. The disclosure of which is consented to by the Acquirer.

F. Respondents shall:

1. No later than the earlier of ten (10) days after a request from the Proposed Acquirer or ten (10) days before the Closing Date, provide to the Proposed Acquirer a list of all Employees and, in compliance with and to the extent permitted by all Laws, and an opportunity to inspect the personnel files and other documentation relating to such Employees. The list of Employees that Respondents shall provide shall include the following information for each Employee, as requested by the Proposed Acquirer, and to the extent permitted by Law:
 - a. Name, job title or position, date of hire by the relevant Respondent, and effective service date;
 - b. Specific description of the employee's responsibilities and primary work location;

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- c. The base salary or current wages;
 - d. Most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, current target or guaranteed annual bonus or commission opportunities and target long term incentive opportunities, if applicable;
 - e. Employment and leave status (*i.e.*, active or on leave or disability; full-time or part-time; reason for leave and expected date of return from leave, in each case, if applicable; accrued and unused vacation, sick leave, and personal time off days);
 - f. Any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly-situated employees; and
 - g. At the Proposed Acquirer's option, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the Employee.
- 2. No later than ten (10) days before the Closing Date, allow the Proposed Acquirer an opportunity to meet personally and outside the presence or hearing of any employee or agent of Respondents with any Employee, and to make offers of employment to any one or more of the Employees;
 - 3. Not interfere, directly or indirectly, with the hiring or employing of any Employee by the Proposed Acquirer, not offer any incentive to any Employee to decline employment with the Proposed Acquirer, not make any counter-offer to any Employee who has an outstanding offer of employment from the Proposed Acquirer or who has accepted an offer of employment from the Proposed Acquirer, and not otherwise interfere

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with the recruitment or employment of an Employee by the Proposed Acquirer;

4. Remove any impediments within the control of Respondents that may deter any Employee from accepting employment with the Proposed Acquirer, including, but not limited to, removal of any non-compete or confidentiality provisions of employment or other contracts with Respondents that may affect the ability or incentive of the Employee(s) to accept employment with the Proposed Acquirer;
5. Not, for a period of one (1) year from the Closing Date, directly or indirectly, solicit or otherwise attempt to induce any Employee who has accepted an offer of employment with the Acquirer to terminate his or her employment with the Acquirer; *provided, however*, that Respondents may:
 - a. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, as long as this is not targeted specifically at Employees; or
 - b. Hire Employees who apply for employment with Respondents, as long as such Employees were not solicited by Respondents in violation of this Paragraph II.F.

Provided, however, that this Paragraph II.F. shall not prohibit Respondents from making offers of employment to or employing any Employee after the Closing Date where: (i) the Acquirer has notified Respondents in writing that the Acquirer does not intend to make an offer of employment to that Employee; (ii) the Acquirer has terminated the employment of the Employee; or (iii) where the Employee's employment with the Acquirer ended for any reason more than ninety (90) days prior to Respondents' solicitation of the Employee.

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- G. Pending divestiture of the Assets To Be Divested, Respondents shall take such actions as are necessary to maintain the viability, marketability, and competitiveness of the Assets To Be Divested, and to prevent the destruction, removal, deterioration, or impairment of any of the Assets To Be Divested.
- H. The purpose of the divestiture of the Assets To Be Divested is to ensure the continued use of the assets in the same Businesses in which the Assets To Be Divested were engaged at the time of the announcement of the proposed Acquisition by Respondents and to remedy the lessening of competition alleged in the Commission's complaint.

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

- A. Edward J. Buthusiem shall serve as Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreement, including any Transition Services Agreement and Transitional Manufacturing and Supply Agreement, approved by the Commission.
- B. No later than one (1) day after the Acquisition Date, Respondents shall enter into the Monitor Agreement that is attached as Appendix II and Confidential Appendix II-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 rights, powers, and authorities necessary to permit the Monitor to perform his/her 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 responsibility and the power and authority to monitor Respondents'

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compliance with the terms of the Orders and the Remedial Agreement, including any Transition Services Agreement and Transitional Manufacturing and Supply Agreement, 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, in consultation with the Commission or its staff, including any directive from the Commission to the Respondents to effect such modifications to the manner of divestiture of the Assets to be Divested as are necessary to satisfy the requirements of this Order;

2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
3. The Monitor shall serve for such time as is necessary to monitor Respondents' compliance with the provisions of the Orders and the Remedial Agreement, including for as long as Respondents are providing Transition Services to the Acquirer pursuant to a Transition Services Agreement or supplying VCD Products or VCD Components to the Acquirer pursuant to a Transitional Manufacturing and Supply Agreement; *provided, however,* that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders;
4. 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 Respondents' compliance with their obligations under the Orders and the Remedial Agreement. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with

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or impede the Monitor's ability to monitor Respondents' compliance with the Orders and the Remedial Agreement;

5. 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;
6. 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; and
7. 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 Respondents, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under this Order or the Remedial Agreement. 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 Orders.

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- C. 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.
- D. 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.
- E. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld, as follows: (a) If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor; and (b) not later than ten (10) days after appointment of a substitute Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondents' compliance with the terms of the Orders and the Remedial Agreement.
- F. 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 or the Remedial Agreement.

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- G. The Monitor appointed pursuant to the Orders 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 Respondents have not fully complied with the obligations to divest the Assets to be Divested as required by this Order, the Commission may appoint a Divestiture Trustee to divest the Assets to be Divested and/or perform Respondents' other obligations 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 Section 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 divest the relevant 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 Section 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 the 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 identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

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- C. No 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(s) 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 relevant assets or rights that are required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by this Order;
 - 2. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described herein to accomplish the divestiture(s), which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve-month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed Divestiture Trustee, by the court; *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 that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by the

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Order, or 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 best efforts to negotiate the most favorable price and terms available in the 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 entity for any of the Assets to be Divested, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; *provided further* that Respondents shall select such entity 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 Respondents, such consultants, accountants, attorneys, investment bankers, business brokers,

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appraiser, 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(s) and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, 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 the 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 assigned, granted, licensed, divested, transferred delivered or otherwise conveyed 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 the Orders;

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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(s); and
 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*, 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, for a period of ten (10) years from the date this Order is issued, Respondents shall not, acquire, directly or indirectly, through subsidiaries or otherwise, any ownership, leasehold, or other interest, in whole or in part, in ACT or the assets of the ACT, without providing advance written notice to the Commission.

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The prior notification required by this Paragraph shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as the "Notification"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification; Notification shall be filed with the Secretary of the Commission; Notification need not be made to the Department of Justice; and Notification is required only of the Respondents and not of any other party to the transaction. Respondents shall provide two (2) complete copies (with all attachments and exhibits) of the Notification to the Commission at least thirty (30) days prior to consummating any such transaction (hereafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 802.20), Respondents shall not consummate the transaction until thirty (30) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested by Respondents and, where appropriate, granted by a letter from the Commission's Bureau of Competition; *provided however*, that prior notification shall not be required by this Paragraph for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

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

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- 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 a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the

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full scope and breadth of each Respondent's obligations to the Acquirer(s) pursuant to this Order.

- D. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to the Assets to be Divested, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- E. 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.

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

- A. Within five (5) days of the Acquisition, Respondents shall submit a letter certifying the date on which the Acquisition occurred (the "Acquisition Date").
- B. Within ten (10) days after the date this Order is issued, Respondents shall provide a copy of this Order to each of Respondents' officers, employees, or agents having managerial responsibility for any of Respondents' obligations under Paragraphs II through V of this Order.
- C. Within thirty (30) days after the date this Order is issued, and every thirty (30) days thereafter until Respondents have fully complied with Paragraphs II.A. and II.B. of this Order, and every sixty (60) days

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thereafter until Respondents have fully complied with Paragraphs II.C., II.D., II.E.1., II.E.2., II.E.3., II.E.6., II.F.1., II.F.2., II.F.3., II.F.4., II.G., III., VII.A., and VII.B. of this Order, 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 this Order. Respondents shall include in their reports, among other things that are required from time to time: (1) a full description of the efforts being made to comply with this Order; (2) a detailed description of the plans and actions taken to divest and transfer the relevant assets and rights; (3) a detailed description of the plans and actions taken to deliver all Confidential Business Information to the Acquirer; and (4) a description of Respondents' provision of Transition Services and Products pursuant to the Remedial Agreement, including any Transition Services Agreement and Transitional Manufacturing and Supply Agreement.

- D. Respondents shall submit to the Monitor, if one has been appointed, a copy of each report at the same time such report is submitted to the Commission.
- E. One (1) year after the date this Order is issued, annually for the next nine (9) years on the anniversary of the date this Order is issued, 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 they have complied and are complying with this Order. Respondents shall submit at the same time a copy of these reports to the Monitor.

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;

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

IX.

IT IS FURTHER ORDERED that, for the purpose 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, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during office hours of the 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 Respondents relating to compliance with this Order, which copying services shall be provided by Respondents at their expense; and
- B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order shall terminate on February 14, 2027.

By the Commission.

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Confidential Appendix I

Terumo Purchase Agreement

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Confidential Appendix I-1

Letter Agreement

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Appendix II

Monitor Agreement

Confidential Appendix II-1

Appendix to Monitor Agreement

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Analysis to Aid Public Comment

**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 Abbott Laboratories (“Abbott”) and St. Jude Medical, Inc. (“St. Jude”) that is designed to remedy the anticompetitive effects that otherwise would have resulted from Abbott’s proposed acquisition of St. Jude. Under the terms of the proposed Consent Agreement, the parties are required to divest St. Jude’s vascular closure device business and Abbott’s steerable sheath business to Terumo Corporation (“Terumo”). Abbott is also required to provide notice if it intends to acquire the assets of Advanced Cardiac Therapeutics, Inc. (“ACT”).

The Consent Agreement has been placed on the public record for thirty days to solicit comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the Consent Agreement, along with the comments received, and decide whether it should withdraw from the Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Pursuant to an Agreement and Plan of Merger dated April 27, 2016, Abbott proposes to acquire St. Jude in exchange for cash and stock valued at approximately \$25 billion (the “Proposed 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 lessening competition in the U.S. markets for vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition.

Analysis to Aid Public Comment

THE PARTIES

Headquartered in Abbott Park, Illinois, Abbott is a global health care company that offers a large portfolio of vascular products, including coronary, endovascular, vascular closure, electrophysiology, and structural heart devices.

St. Jude, headquartered in St. Paul, Minnesota, is a leading manufacturer of vascular products and medical devices. St. Jude's vascular products include vascular closure devices, pressure measurement guidewires, percutaneous catheter introducers, heart failure monitoring devices, cardiac mapping and navigation systems, diagnostic catheters, ablation catheters, and introducer sheaths.

THE RELEVANT PRODUCTS AND STRUCTURE OF THE MARKETS

Vascular closure devices are used to close arterial holes resulting from vascular catheterization procedures. Physicians perform these catheterization procedures to diagnose or treat a cardiovascular condition. Typically, physicians access the femoral artery and direct a specialized catheter to the heart or peripheral arteries to deploy a balloon, diagnose an arrhythmia, or insert a stent or other device. The procedures leave a hole in the artery that must be closed quickly after the catheter is removed. Vascular closure devices provide a fast and effective way for physicians to close these holes while minimizing complications and the time patients must spend recovering from the procedure. Abbott and St. Jude are the two largest suppliers of vascular closure devices in the United States, with a combined market share of over 70%. The only other firms that supply vascular closure devices in the U.S. market are Cardinal Health, Inc. and Cardiva Medical, Inc.

Steerable sheaths are used in electrophysiology procedures to treat complex heart arrhythmias, such as atrial fibrillation. Unlike a fixed sheath, the tip of a steerable sheath is deflectable, which provides better maneuverability and stability for an ablation catheter. Steerable sheaths allow physicians to more easily puncture the transseptal wall of the heart and guide the sheath and catheter into the left atrium or ventricle of the heart. St. Jude is,

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by far, the largest supplier of steerable sheaths in the U.S. market. Abbott recently entered this market through its acquisition of Kalila Medical, Inc. (“Kalila”) in early 2016. Other suppliers in this market, though not recent entrants, have low single-digit market shares.

Lesion-assessing ablation catheters are used during ablation procedures to treat heart arrhythmias. They also provide feedback to physicians regarding the force being applied by the catheter or the temperature of the ablation target. These products are becoming more important, and more frequently used, as physicians treat more cases of complex atrial fibrillation. Currently, only St. Jude and Biosense Webster Inc. (“Biosense”) provide lesion-assessing ablation catheters in the United States. Abbott and ACT entered into a strategic partnership to develop lesion-assessing ablation catheters.

The United States is the relevant geographic market in which to assess the competitive effects of the Proposed Acquisition. Vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters are all medical devices that are regulated by the FDA. Products that are sold outside the United States, but not approved for sale in the United States, are not alternatives for U.S. consumers.

EFFECTS OF THE ACQUISITION

The Proposed Acquisition would cause significant competitive harm in the U.S. markets for vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters. For vascular closure devices, the merger would combine the largest and second-largest suppliers in the United States. The merger would eliminate the substantial price competition that currently exists between these competitors.

In the market for steerable sheaths, St. Jude is currently the largest supplier in the United States and has held a near-monopoly position in this market for over a decade. Abbott entered this market recently and its product is well positioned to compete head-to-head with St. Jude. The Proposed Acquisition would eliminate the competition that would have occurred between Abbott and St. Jude in this market.

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Finally, if Abbott acquires ACT's lesion-assessing ablation catheter assets, it could eliminate potential competition in the U.S. market for lesion-assessing ablation catheters. ACT's lesion-assessing ablation catheter currently in development would compete directly with offerings from St. Jude and Biosense. It would thus be the third competitor in the highly-concentrated U.S. market for lesion-assessing ablation catheters. Abbott's acquisition of the ACT assets would reduce the additional competition that would have resulted from an additional U.S. supplier of lesion-assessing ablation catheters.

ENTRY

Entry into the U.S. markets for vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The development process for each of these devices is difficult, time-consuming, and expensive. It can take tens of millions of dollars of research and development, significant further funding for clinical trials, and an extensive amount of time to even reach the stage of applying to the FDA for approval. The regulatory approval process itself can also be time-consuming as the FDA reviews the volume of material and data a company submits in support of its application.

THE CONSENT AGREEMENT

The Consent Agreement remedies the competitive concerns raised by Abbott's proposed acquisition of St. Jude by requiring that the parties divest to Terumo all of the assets and resources needed for it to become an independent, viable, and effective competitor in the U.S. markets for vascular closure devices and steerable sheaths. It also requires Abbott to provide notice if it intends to acquire ACT's lesion-assessing ablation catheter assets.

Terumo possesses the industry experience and reputation necessary to replace competition that would be lost in the U.S. markets for vascular closure devices and steerable sheaths. Terumo is headquartered in Tokyo, Japan. It has been active in the U.S. medical device market for over thirty years and has a U.S. subsidiary based in Somerset, New Jersey. Terumo offers a

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portfolio of products that are highly complementary to the vascular closure and steerable sheath products being acquired but does not sell any competing products. Through its Interventional Systems business unit, Terumo manufactures and sells guidewires, catheters, and sheaths, as well as other vascular access devices. As a result, it currently sells its products to many of the same customers as Abbott and St. Jude. Terumo is thus well positioned to restore the benefits of competition that would be lost through the Proposed Acquisition.

Pursuant to the Order, Terumo will receive all rights and assets related to St. Jude's vascular closure device business and Abbott's steerable sheath business, including all of the intellectual property used in those businesses. In addition, Terumo will take over part of the facility in Caguas, Puerto Rico where St. Jude currently manufactures most of its vascular closure device products. In order to ensure continuity of supply for certain vascular closure devices and components that are not currently manufactured in the Puerto Rico facility, the Order requires that St. Jude supply Terumo with finished vascular closure devices and components for up to two years while Terumo transitions to independent manufacturing.

To ensure that the divestiture is successful, the Order requires the parties to enter into a transitional services agreement with Terumo to assist the company in establishing its manufacturing capabilities. Further, the Order requires that the parties transfer all confidential business information to Terumo, as well as provide access to employees who possess or are able to identify such information. Terumo also will have the right to interview and offer employment to employees associated with St. Jude's vascular closure device business and Abbott's steerable sheath business.

The parties must accomplish the divestiture no later than forty-five days after the consummation of the Proposed Acquisition. If the Commission determines that Terumo is not an acceptable acquirer, or that the manner of the divestiture is not acceptable, the Order requires the parties to unwind the sale and accomplish the divestiture within 180 days of the date the Order becomes final to another Commission-approved acquirer.

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To ensure compliance with the Order, the Commission has agreed to appoint an Interim Monitor to ensure that Abbott and St. Jude 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 Terumo. Further, the Order allows the Commission to appoint a Divestiture Trustee to accomplish the divestiture should the parties fail to comply with their divestiture obligations. Lastly, the Order terminates after ten years.

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

Complaint

IN THE MATTER OF

**COOPERATIVA DE MÉDICOS
OFTALMÓLOGOS DE PUERTO RICO**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4603; File No. 141 0194**Complaint, February 27, 2017 – Decision, February 27, 2017*

This consent order addresses Cooperativa de Médicos Oftalmólogos de Puerto Rico's agreement among competing ophthalmologists to refuse to deal with MCS Advantage, Inc., a payor, and Eye Management of Puerto Rico, MCS's network administrator. The complaint alleges that Cooperativa de Médicos Oftalmólogos de Puerto Rico violated Section 5 of the Federal Trade Commission Act by orchestrating a concerted refusal to deal by ophthalmologists in Puerto Rico to preclude a third-party payor and its network administrator from implementing a cost-savings program to manage ophthalmology services and reduce reimbursement rates. The consent order prohibits Cooperativa de Médicos Oftalmólogos de Puerto Rico from organizing or implementing agreements to refuse to deal, or to threaten to refuse to deal, with a payor over contract terms, as well as agreements not to deal individually with payors, or to deal only through Cooperativa de Médicos Oftalmólogos de Puerto Rico.

Participants

For the *Commission*: Robert S. Canterman, Synda Mark, Gary H. Schorr, and Steve Vieux.

For the *Respondent*: Omar Martinez, Martinez & Martinez; Luis Martinez; Veronica Ferraiuoli, Estudio Legal Ferraiuoli; David Balto and Bradley A Wasser, Law Offices of David A. Balto.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41, *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Cooperativa de Médicos Oftalmólogos de Puerto Rico ("OFTACOO"), hereinafter referred to as "Respondent," has violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it