

**UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION**

**COMMISSIONERS:**      **Lina M. Khan, Chair**  
                                  **Noah Joshua Phillips**  
                                  **Rebecca Kelly Slaughter**  
                                  **Christine S. Wilson**

In the Matter of	)	
	)	
<b>Medtronic plc,</b>	)	<b>DECISION AND ORDER</b>
a public limited company,	)	<b>Docket No. C-4763</b>
	)	
<b>Medtronic, Inc.,</b>	)	
a corporation, and	)	
	)	
<b>Intersect ENT, Inc.,</b>	)	
a corporation.	)	

**DECISION**

The Federal Trade Commission initiated an investigation of the proposed acquisition by Respondent Medtronic, Inc., a wholly owned subsidiary of Respondent Medtronic plc, of Respondent Intersect ENT, Inc. (collectively “Respondents”). The Commission’s Bureau of Competition prepared and furnished to Respondents the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint 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 (collectively “Acts”).

Respondents and the Bureau of Competition executed an Agreement Containing Consent Orders (“Consent Agreement”) containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint, (2) 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 the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true, (3) waivers and other provisions as required by the Commission’s Rules, and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and 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. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same

time, it issued and served its Complaint and Order to Maintain Assets. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Medtronic plc is a public limited company organized, existing, and doing business under and by virtue of the laws of Ireland, with its executive offices and principal place of business located at 20 Lower Hatch Street, Dublin 2, and its United States address for service of process is 710 Medtronic Parkway, Minneapolis, Minnesota 55432.
2. Respondent Medtronic, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Minnesota, with its executive offices and principal place of business located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.
3. Respondent Intersect ENT, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its executive offices and principal place of business located at 1555 Adams Drive, Menlo Park, California 94025.
4. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

## **ORDER**

### **I. Definitions**

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

- A. “Medtronic plc” means Medtronic plc, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, including Medtronic, Inc., partnerships, divisions, groups, and affiliates controlled by Medtronic plc, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- B. “Medtronic” means Medtronic, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Medtronic, Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- C. “Intersect” means Intersect ENT, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Intersect ENT, Inc., and the respective

directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

- D. “Hemostasis” means Hemostasis, LLC, a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its executive offices and principal place of business located at 5000 Township Parkway, St. Paul, Minnesota 55110.
- E. “Commission” means the Federal Trade Commission.
- F. “Acquirer” means:
  - 1. Hemostasis; or
  - 2. Any other Person that the Commission approves to acquire the Fiagon Assets pursuant to this Order.
- G. “Acquisition” means the proposed acquisition described in the Agreement and Plan of Merger dated as of August 6, 2021, by and among Medtronic, Inc., Project Kraken Merger Sub, Inc., and Intersect ENT, Inc.
- H. “Acquisition Date” means the date Respondents consummate the Acquisition.
- I. “Business Information” means books, records, data, and information, wherever located and however stored, used in or related to the Fiagon Assets and Fiagon Business, including electronic medical records, documents, written information, graphic materials, and data, and data and information in electronic format. Business Information includes records and information relating to sales, marketing, advertising, personnel, accounting, business strategy, information technology systems, customers, suppliers, research and development, registrations, licenses, permits (to the extent transferable), manufacturing and operations. Business Information includes Confidential Business Information.
- J. “Confidential Business Information” means all Business Information that is not in the public domain, except for any information that was or becomes generally available to the public other than as a result of disclosure by Respondents.
- K. “Contract” means an agreement, mutual understanding, arrangement, license agreement, lease, consensual obligation, commitment, promise, or undertaking, whether written or oral, express or implied, or legally binding or not.
- L. “Direct Cost” means a cost not to exceed the actual cost of labor, materials, travel, and other expenditures. The cost of any labor included in Direct Cost shall not exceed the then-current average hourly wage rate for the employee providing such labor.

M. “Divestiture Agreement” means:

1. Sale and Purchase Agreement dated March 23/24/25, 2022, by and among Intersect ENT, Inc., and Hemostasis, LLC, and all amendments, exhibits, attachments, agreements, and schedules thereto;
2. Transitional Services Agreement dated March 24/25, 2022, by and among Intersect ENT, Inc., Intersect ENT International GmbH, Intersect ENT GmbH, and Fiagon NA LLC, and all amendments, exhibits, attachments, agreements, and schedules thereto; or
3. Any agreement between a Respondent (or a Divestiture Trustee) and an Acquirer to purchase the Fiagon Assets, and all amendments, exhibits, attachments, agreements, and schedules thereto.

The Divestiture Agreements are contained in Nonpublic Appendix A.

N. “Divestiture Date” means the date on which Respondents (or a Divestiture Trustee) consummate the divestiture of the Fiagon Assets as required by Section II of this Order.

O. “Divestiture Trustee” means the Person appointed by the Commission pursuant to Section IX of this Order.

P. “Employee Information” means for each Fiagon Employee, to the extent permitted by law, the following information summarizing the employment history of each employee that includes:

1. Name, job title or position, date of hire, and effective service date;
2. Specific description of the employee’s responsibilities;
3. The base salary or current wages;
4. Most recent bonus paid, aggregate annual compensation for Respondent’s last fiscal year, and current target or guaranteed bonus, if any;
5. Written performance reviews for the past three years, if any;
6. Employment status (*i.e.*, active or on leave or disability; full-time or part-time);
7. Any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
8. At the Acquirer’s option, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the employee.

- Q. “FDA” means the United States Food and Drug Administration.
- R. “Fiagon Assets” mean Respondents’ rights, title, and interests in and to all tangible and intangible assets, wherever located, used in or relating to each Fiagon Product and the Fiagon Business, including all:
1. Intellectual Property;
  2. Real property interests, whether owned or leased, together with all easements, rights of way, buildings, improvements, Fiagon Facilities, parking lots, and appurtenances thereto;
  3. Tangible personal property, including all fixtures, furnishings, machinery, equipment, computer hardware, supplies, and inventories;
  4. Intangible rights and property including going concern value and goodwill;
  5. Rights under any and all Contracts, at the option of the Acquirer;
  6. Business Information; and
  7. Governmental Permits and all pending applications or renewals thereof, including from and to the FDA.
- S. “Fiagon Business” means all business conducted by Respondent Intersect prior to the Acquisition Date relating to the research, development, manufacture, marketing, sale, and distribution of Fiagon Products.
- T. “Fiagon Employees” mean any and all full-time, part-time, or contract individuals employed by Respondent Intersect at any time since August 6, 2021, whose job responsibilities relate or related to any aspect of the Fiagon Business.
- U. “Fiagon Facilities” mean:
1. 3913 Todd Lane, Building 100, Suite 101, Austin, Texas 78744; and
  2. Neuendorfstrasse 23B, 16761 Hennigsdorf, Germany.
- V. “Fiagon Products” mean all balloon sinus dilation products and ear, nose, and throat (“ENT”) navigation systems developed or in development, manufactured, assembled, marketed, sold, owned, or controlled by Fiagon AG Medical Technologies either before or after it was acquired by Respondent Intersect, including VenSure, VirtuDrive CUBE4D, VirtuEye, and VirtuLink product lines, all products and supplies related thereto, and any pipeline products.

- W. “Governmental Permit” means all consents, licenses, permits, approvals, registrations, certificates, rights, or other authorizations from any governmental entity necessary to effect the complete transfer and divestiture of the Fiagon Assets to the Acquirer and for such Acquirer to operate the Fiagon Business. Governmental Permits includes all communications with the FDA.
- X. “Intellectual Property” means all intellectual property of any kind, including patents, patent applications, mask works, trademarks, service marks and applications, copyrights, trade dress, commercial names, trade names, inventions, discoveries, written and unwritten know-how, customer lists, trade secrets, proprietary information, internet web sites, internet domain names, social media, and all content related exclusively to the Fiagon Products and Fiagon Business that is displayed on any website.
- Y. “Monitor” means any Person appointed by the Commission to serve as a monitor pursuant to the Orders.
- Z. “Orders” mean this Order and the Order to Maintain Assets entered in this action.
- AA. “Person” means any individual, partnership, corporation, business trust, limited liability company, limited liability partnership, joint stock company, trust, unincorporated association, joint venture, governmental body, or other entity.
- BB. “Third Party” means any Person other than the Respondents or the Acquirer.
- CC. “Transition Assistance” 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 Fiagon Assets to the Acquirer, including support related to audits, finance and accounting, human resources, information technology and systems, maintenance and repair of Fiagon Facilities and equipment, manufacturing, manufacturing, purchasing quality control, research and development, technology transfer, regulatory compliance, sales and marketing, customer service, supply chain management, and custom transfer logistics.

## II. Divestiture

**IT IS FURTHER ORDERED** that:

- A. No later than 10 days after the Acquisition Date, Respondents shall divest the Fiagon Assets, absolutely and in good faith, as an ongoing business, to Hemostasis.
- B. If Respondents have divested the Fiagon Assets to Hemostasis prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that:
1. Hemostasis is not acceptable as the acquirer of the Fiagon Assets, then Respondents shall immediately rescind the Divestiture Agreements, and shall

divest the Fiagon Assets no later than 120 days from the date this Order is issued, absolutely and in good faith, at no minimum price, to a Person that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission; or

2. The manner in which the divestiture of the Fiagon Assets to Hemostasis 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 Fiagon Assets as the Commission may determine are necessary to satisfy the requirements of this Order.
- C. Respondents shall assist the Acquirer to conduct a due diligence investigation of the Fiagon Assets that the Acquirer seeks to purchase, including by providing sufficient and timely access to all information customarily provided as part of a due diligence process, and affording the Acquirer and its representatives (including prospective lenders and their representatives) full and free access, during regular business hours, to the personnel, assets, Contracts, Business Information, and Fiagon Facilities, with such rights of access to be exercised in a manner that does not unreasonably interfere with the operations of Respondents.
- D. Respondents shall obtain, prior to the Divestiture Date and at their sole expense, all consents from Third Parties and all Governmental Permits that are necessary to effect the complete transfer and divestiture of the Fiagon Assets to the Acquirer and for the Acquirer to operate all aspects of the Fiagon Business;

*Provided, however, that:*

1. Respondents may satisfy the requirement to obtain all consents from Third Parties by certifying that the Acquirer has entered into equivalent agreements or arrangements directly with the relevant third party that are acceptable to the Commission, or has otherwise obtained all necessary consents and waiver; and
  2. With respect to any Governmental Permits relating to the Fiagon Assets that are not transferable or not transferred on the Divestiture Date, Respondents shall, to the extent permitted under applicable law, allow the Acquirer to operate the Fiagon Assets under Respondents' Governmental Permits pending the Acquirer's receipt of its own Governmental Permits, and Respondents shall provide such assistance as the Acquirer may reasonably request in connection with its efforts to obtain such Governmental Permits.
- E. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against the Fiagon Products under any patent that was pending or issued on or before the Acquisition Date if such suit would limit or impair the Acquirer's freedom to manufacture, distribute, market, sell, or offer for sale any Fiagon Products anywhere in the world, including new versions of the Fiagon Products.

- F. Upon written notice from an Acquirer to Respondents, Respondents shall assist, in a timely manner and at no greater than Direct Cost, the Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to Intellectual Property related to a Fiagon Product acquired by the Acquirer pursuant to Section II.
- G. For any lawsuit related to a Fiagon Product that is filed prior to the Divestiture Date, in which Respondent Intersect is alleged to have infringed the Intellectual Property of a Third Party, which Respondent Intersect has prepared or is preparing to defend against as of the Divestiture Date, Respondents shall:
  - 1. Cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses in a timely manner and at their sole expense in connection with obtaining resolution of any pending patent litigation related to that Fiagon Product;
  - 2. Waive conflicts of interest, if any, to allow Respondents' outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Fiagon Product; and
  - 3. Permit the transfer to the Acquirer of all of the litigation files and any related attorney work product in the possession of Respondents' outside counsel related to that Fiagon Product.

### **III. Divestiture Agreements**

**IT IS FURTHER ORDERED** that:

- A. The Divestiture Agreements shall be incorporated by reference into this Order and made a part hereof, and any failure by Respondents to comply with the terms of the Divestiture Agreements shall constitute a violation of this Order;  
  
*Provided, however,* that the Divestiture Agreements shall not limit, or be construed to limit, the terms of this Order. To the extent any provision in the Divestiture Agreements varies from or conflicts with any provision in this Order such that Respondents cannot fully comply with both, Respondents shall comply with the Order.
- B. Respondents shall not modify or amend the terms of the Divestiture Agreements after the Commission issues this Order without the prior approval of the Commission, except as otherwise provided in Commission Rule 2.41(f)(5), 16 C.F.R. § 2.41(f)(5).

#### **IV. Transition Assistance**

**IT IS FURTHER ORDERED** that:

- A. Until Respondents have transferred all Business Information included in the Fiagon Assets, Respondents shall ensure that the Business Information is maintained and updated in the ordinary course of business and shall provide the Acquirer with access to records and information (wherever located and however stored) that Respondents have not yet transferred to the Acquirer, and to employees who possess the records and information.
- B. Respondents shall provide the Acquirer with Transition Assistance sufficient to (1) efficiently transfer the Fiagon Assets to the Acquirer, and (2) assist the Acquirer in operating the Fiagon Assets and Fiagon Business in all material respects in the manner in which Respondent Intersect did so prior to the Acquisition.
- C. Respondents shall provide such Transition Assistance:
  - 1. As set forth in the Divestiture Agreements, or as otherwise reasonably requested by the Acquirer (whether before or after the Divestiture Date);
  - 2. At Direct Cost; and
  - 3. For a period sufficient to meet the requirements of Section IV, which shall be, at the option of the Acquirer, for one year after the Divestiture Date;

*Provided, however,* that within 15 days after a request by the Acquirer, Respondents shall file with the Commission a written request to extend the time period for providing Transition Assistance in order to achieve the purposes of this Order.

- D. Respondents shall allow the Acquirer to terminate, in whole or part, any Transition Assistance provisions of the Divestiture Agreements upon commercially reasonable notice and without cost or penalty.
- E. Respondents shall not cease providing Transition Assistance due to a breach by the Acquirer of the Divestiture Agreements, and shall not limit any damages (including indirect, special, and consequential damages) that the Acquirer would be entitled to receive in the event of Respondents' breach of the Divestiture Agreements.

#### **V. Employees**

**IT IS FURTHER ORDERED** that:

- A. Until 6 months after the Divestiture Date, Respondents shall cooperate with and assist the Acquirer of the Fiagon Assets to evaluate independently and offer employment to the Fiagon Employees.

B. Respondents shall:

1. No later than 10 days after a request from the Acquirer, provide to the Acquirer a list of all Fiagon Employees and provide Employee Information for each;
2. No later than 10 days after a request from the Acquirer, provide the Acquirer an opportunity to meet outside the presence or hearing of any employee or agent of Respondents with any of the Fiagon Employees, and to make offers of employment to any of the Fiagon Employees;
3. Remove any impediments within the control of Respondents that may deter Fiagon Employees from accepting employment with the Acquirer, including removal of any noncompete or confidentiality provisions of employment or other Contracts with Respondents that may affect the ability or incentive of those individuals to be employed by the Acquirer, and shall not make any counteroffer to a Fiagon Employee who receives an offer of employment from the Acquirer;

*Provided, however,* that nothing in this Order shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee;

4. Continue to provide Fiagon Employees compensation and benefits, including regularly scheduled raises and bonuses and the vesting of benefits while they are employed by Respondents; and
5. Not interfere, directly or indirectly, with the hiring or employing by the Acquirer of any Fiagon Employee, not offer any incentive to such employees to decline employment with the Acquirer, and not otherwise interfere with the recruitment of any Fiagon Employee by the Acquirer.

C. Respondents shall provide financial incentives for Fiagon Employees to continue in their positions and, as may be necessary, to facilitate their employment by the Acquirer.

D. Respondents shall not, for a period of 180 days following the Divestiture Date, directly or indirectly, solicit or otherwise attempt to induce any of the Fiagon Employees who have accepted offers of employment with the Acquirer to terminate his or her employment with the Acquirer;

*Provided, however,* Respondents may:

1. Hire an employee whose employment has been terminated by the Acquirer;
2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more Fiagon Employees; or
3. Hire an employee who has applied for employment with Respondents, as long as

such application was not solicited or induced in violation of Section V.

## **VI. Asset Maintenance**

**IT IS FURTHER ORDERED** that Respondents shall, subject to their obligations under the Order to Maintain Assets, ensure that the Fiagon Assets are operated and maintained in the ordinary course of business consistent with past practices until such assets are fully transferred to the Acquirer, and shall:

- A. Take all actions necessary to maintain the full economic viability, marketability, and competitiveness of the Fiagon Business and related Fiagon Assets, to minimize the risk of any loss of their competitive potential, to operate them in a manner consistent with applicable laws and regulations, and to prevent their destruction, removal, wasting, deterioration, or impairment (other than as a result of ordinary wear and tear);
- B. Not sell, transfer, encumber, or otherwise impair the Fiagon Business and related Fiagon Assets (other than in the manner prescribed in the Orders), or take any action that lessens their full economic viability, marketability, or competitiveness;
- C. Not terminate the operations of the Fiagon Business and related Fiagon Assets, and shall conduct or cause to be conducted the operations of the Fiagon Business and related Fiagon Assets in the ordinary course of business and in accordance with past practice (including regular repair and maintenance efforts) and as may be necessary to preserve the full economic viability, ongoing operations, marketability, and competitiveness of the Fiagon Business and related Fiagon Assets; and
- D. Use best efforts to preserve the existing relationships with suppliers, customers, employees, governmental authorities, vendors, landlords, and others having business relationships with the Fiagon Business and related Fiagon Assets.

*Provided, however,* that Respondents may take actions that the Acquirer has requested or agreed to in writing and that have been approved in advance by Commission staff, in all cases to facilitate the Acquirer's acquisition of the Fiagon Assets and consistent with the purposes of this Order and the Order to Maintain Assets.

## **VII. Confidentiality**

**IT IS FURTHER ORDERED** that:

- A. Respondents shall not disclose (including to Respondents' employees), and not use, for any reason or purpose, any Confidential Business Information received or maintained by Respondents;

*Provided, however,* that Respondents may disclose or use such Confidential Business Information in the course of:

1. Performing their obligations or as permitted under this Order, the Order to Maintain Assets, or the Divestiture Agreements; or
  2. Complying with financial reporting requirements, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions threatened or brought against the Fiagon Assets or Fiagon Business, or as required by law.
- B. Respondents shall only disclose Confidential Business Information to an employee or any other Person if disclosure is permitted in Paragraph VII.A and the employee or other Person has signed an agreement to maintain the confidentiality of such information and not violate the disclosure requirements of this Order.
- C. Respondents shall enforce the terms of Section VII and take necessary actions to ensure that their employees or other Persons comply with its terms, including implementing access and data controls, training of employees, and taking other actions that Respondents would take to protect their own trade secrets and proprietary information.

### **VIII. Monitor**

**IT IS FURTHER ORDERED** that:

- A. The Commission appoints Jeryl Hilleman as the Monitor to observe and report on Respondents' compliance with their obligations as set forth in the Orders.
- B. The Respondents and the Monitor may enter into an agreement relating to the Monitor's services. Any such agreement:
1. Shall be subject to the approval of the Commission;
  2. Shall not limit, and the signatories shall not construe it to limit, the terms of Section VIII or the Section relating to the Monitor in the Order to Maintain Assets ("Monitor Sections"), and to the extent any provision in the agreement varies from or conflicts with any provision in the Monitor Sections, Respondents and the Monitor shall comply with the Monitor Sections; and
  3. Shall include a provision stating that the agreement does not limit, and the signatories shall not construe it to limit, the terms of the Orders in this matter, and to the extent any provision in the agreement varies from or conflicts with any provision in the Orders, Respondents and the Monitor shall comply with the Orders.
- C. The Monitor shall:
1. Have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;

2. Act in consultation with the Commission or its staff;
3. Serve as an independent third party and not as an employee or agent of Respondents or of the Commission;
4. Serve without bond or other security;
5. At the Monitor's option, employ such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
6. Enter into a non-disclosure or other confidentiality agreement with the Commission related to Commission materials and information received in connection with the performance of the Monitor's duties and require that each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall also enter into a non-disclosure or other confidentiality agreement with the Commission;
7. Notify staff of the Commission, in writing, no later than 5 days in advance of entering into any arrangement that creates a conflict of interest, or the appearance of a conflict of interest, including a financial, professional or personal conflict. If the Monitor becomes aware of a such a conflict only after it has arisen, the Monitor shall notify the Commission as soon as the Monitor becomes aware of the conflict;
8. Report in writing to the Commission concerning Respondents' compliance with the Orders on a schedule set by Commission staff and at any other time requested by Commission staff; and
9. Unless the Commission or its staff determine otherwise, the Monitor shall serve until Commission staff determines that Respondents have satisfied all obligations under Sections II, IV, and VI, and files a final report.

D. Respondents shall:

1. Cooperate with and assist the Monitor in performing his or her duties for the purpose of reviewing Respondents' compliance with their obligations under the Orders, including as requested by the Monitor, (a) providing the Monitor full and complete access to personnel, information, and facilities; and (b) making such arrangements with third parties to facilitate access by the Monitor;
2. Not interfere with the ability of the Monitor to perform his or her duties pursuant to the Orders;

3. Pay the Monitor's fees and expenses as set forth in an agreement approved by the Commission, or if such agreement has not been approved, pay the Monitor's customary fees, as well as expenses the Monitor incurs performing his or her duties under the Orders, including expenses of any consultants, accountants, attorneys, and other representatives and assistants that are reasonably necessary to assist the Monitor in carrying out his or her duties and responsibilities;
  4. Not require the Monitor to disclose to Respondents the substance of the Monitor's communications with the Commission or any other Person or the substance of written reports submitted to the Commission pursuant to the Orders; and
  5. Indemnify and hold the Monitor harmless against any loss, claim, damage, liability, and expense (including attorneys' fees and out of pocket costs) that arises out of, or is connected with, a claim concerning the performance of the Monitor's duties under the Orders, unless the loss, claim, damage, liability, or expense results from gross negligence or willful misconduct by the Monitor.
- E. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement, so long as the agreement does not restrict the Monitor's ability to access personnel, information, and facilities or provide information to the Commission, or otherwise observe and report on the Respondents' compliance with the Orders.
- F. If the Monitor resigns or the Commission determines that the Monitor has ceased to act, has failed to act diligently, or is otherwise unable to continue serving as a Monitor due to the existence of a conflict or other reasons, the Commission may appoint a substitute Monitor. The substitute Monitor shall be afforded all rights, powers, and authorities and shall be subject to all obligations of the Monitor Sections of the Orders. The Commission shall select the substitute Monitor, subject to the consent of the Respondents.
- Respondents:
1. Shall not unreasonably withhold consent to the appointment of the selected substitute Monitor;
  2. Shall be deemed to have consented to the selection of the proposed substitute Monitor if, within 10 days of notice by staff of the Commission of the identity of the proposed substitute Monitor, Respondents have not opposed in writing, including the reasons for opposing, the selection of the proposed substitute Monitor; and
  3. May enter into an agreement with the substitute Monitor relating to the substitute Monitor's services that either (a) contains substantially the same terms as the Commission-approved agreement referenced in Paragraph VIII.B; or (b) receives Commission approval.

- G. 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.

### **IX. Divestiture Trustee**

#### **IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Fiagon Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order.
- B. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under Section IX shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondents to comply with this Order.
- C. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 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.
- D. Not later than 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 relevant divestiture or other action required by this Order. Any failure by Respondents to comply with a trust agreement approved by the Commission shall be a violation of this Order.
- E. If a Divestiture Trustee is appointed by the Commission or a court pursuant to Section IX, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee’s powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed;
2. The Divestiture Trustee shall have one year from the date the Commission approves the trustee trust agreement described herein to accomplish the divestitures, which shall be subject to the prior approval of the Commission. If, however, at the end of the one year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestitures can be achieved within a reasonable time, the divestiture period may be extended by the Commission,

*Provided, however,* the Commission may extend the divestiture period only 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 this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestitures. Any delays in divestitures caused by Respondents shall extend the time for divestitures under Section IX 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 each Contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestitures shall be made in the manner and to Acquirers that receive the prior approval of the Commission as required by this Order,

*Provided, however,* if the Divestiture Trustee receives bona fide offers from more than one acquiring person for a divestiture, and if the Commission determines to approve more than one such acquiring person for the divestiture, the Divestiture Trustee shall divest to the acquiring person selected by Respondents from among those approved by the Commission,

*Provided further,* however, that Respondents shall select such person within 5 days of 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, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of 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 or willful misconduct by the Divestiture Trustee;
  7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the Fiagon Assets required to be divested by this Order;
  8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every 30 days concerning the Divestiture Trustee's efforts to accomplish the divestiture; 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,* that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- F. 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 a confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- G. 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 Section IX, and who will have the same authority and responsibilities of the original Divestiture Trustee pursuant to Section IX.

- H. 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 divestitures and other obligations or action required by this Order.

#### **X. Respondents Prior Approval**

**IT IS FURTHER ORDERED** that Respondents shall not, without prior approval of the Commission, acquire directly or indirectly, through subsidiaries, partnerships, or otherwise, any rights or interests, in whole or in part, in any balloon sinus dilation products or ENT navigation systems.

#### **XI. Acquirer Prior Approval**

**IT IS FURTHER ORDERED** that:

- A. For a period of 3 years after the Divestiture Date, neither Hemostasis nor any other Acquirer shall sell or otherwise convey to any Person, through subsidiaries or otherwise, without the prior approval of the Commission, any of the Fiagon Assets that were divested pursuant to Section II; and
- B. For a period of 7 years after the term of Paragraph XI.A ends, neither Hemostasis nor any other Acquirer shall sell or convey, through subsidiaries or otherwise, without the prior approval of the Commission, any of the Fiagon Assets that were divested pursuant to Section II, to any Person engaged in the research, development, manufacture, marketing, or sale of any balloon sinus dilation products or ENT navigation systems;

*Provided, however,* Hemostasis is not required to obtain prior approval of the Commission under this Section XI for a change of control, merger, reorganization, or sale of all or substantially all of its business.

#### **XII. Compliance Reports**

**IT IS FURTHER ORDERED** that:

- A. Respondents shall:
1. Notify Commission staff via email at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov) of the Acquisition Date and Divestiture Date no later than 5 days after the occurrence of each; and
  2. Submit the complete Divestiture Agreements to the Commission at [ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov) and [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov) no later than 30 days after the Divestiture Date.

- B. Respondents shall submit verified written reports (“compliance reports”) in accordance with the following:
1. Respondents shall submit:
    - a. Interim compliance reports 30 days after this Order is issued and every 30 days thereafter until Respondents have fully complied with the provisions of Sections II, IV, and VI;
    - b. Annual compliance reports one year after the date this Order is issued, and annually for the next 9 years on the anniversary of that date; and
    - c. Additional compliance reports as the Commission or its staff may request.
  2. Each compliance report shall contain sufficient information and documentation to enable the Commission to determine independently whether Respondents are in compliance with this Order and the Order to Maintain Assets. Conclusory statements that Respondents have complied with their obligations under the Orders are insufficient. Respondents shall include in their reports, among other information or documentation that may be necessary to demonstrate compliance, a full description of the measures Respondents have implemented and plan to implement to comply with each paragraph of the Orders, including detailed descriptions related to:
    - a. The transfer and delivery to the Acquirer of the Fiagon Assets and Fiagon Business;
    - b. Any transitional services being provided by Respondents to the Acquirer; and
    - c. The timing for the completion of such obligations.
  3. For a period of 5 years after filing a compliance report, each Respondent shall retain all material written communications with each party identified in the compliance report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling Respondents’ obligations under the Orders and provide copies of these documents to Commission staff upon request.
- C. Respondents shall verify each compliance report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or another officer or employee specifically authorized to perform this function. Respondents shall file their compliance reports with the Secretary of the Commission at [ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov) and the Compliance Division at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov), as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a). In addition, Respondents shall provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter.

### **XIII. Change in Respondents**

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

- A. The proposed dissolution of Medtronic plc or Medtronic, Inc., respectively;
- B. The proposed acquisition, merger, or consolidation of Medtronic plc or Medtronic, Inc.;  
or
- C. Any other change in Respondents, including assignment and the creation, sale, or dissolution of subsidiaries, if such changes may affect compliance obligations arising out of this Order.

### **XIV. Access**

**IT IS FURTHER ORDERED** that for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, upon written request and 5 days' notice to the relevant Respondent, made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters office, the notified Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

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

### **XV. Purpose**

**IT IS FURTHER ORDERED** that the purpose of this Order is to remedy the harm to competition the Commission alleged in its Complaint, create a viable and effective competitor with the Fiagon Business that is independent of Respondents, and ensure the Acquirer can operate the Fiagon Assets and Fiagon Business at least equivalent in all material respects to the manner in which Respondent Intersect operated the Fiagon Assets and Fiagon Business prior to the Acquisition.

**XVI. Term**

**IT IS FURTHER ORDERED** that this Order shall terminate 10 years from the date it is issued.

By the Commission.

April J. Tabor  
Secretary

SEAL:  
ISSUED:

**Nonpublic Appendix A**

**Divestiture Agreements**

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