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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Maureen K. Ohlhausen, Acting Chairman**
Terrell McSweeny

In the Matter of	)	
INTEGRA LIFESCIENCES HOLDINGS CORPORATION, a corporation;	)	
and	)	**Docket No. C-4624**
JOHNSON & JOHNSON, a corporation.	)	

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of the

1. Natus, if approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective; or

2. Any other Person approved by the Commission to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

F. "Acquisition" means Integra's acquisition of the Transferred Assets pursuant to the Acquisition Agreement.

G. "Acquisition Agreement" means the Asset Purchase Agreement dated as of February 14, 2017, between Depuy Synthes, Inc. and Integra LifeSciences Holdings Corporation that was submitted by Integra to the Commission in this matter. The Acquisition Agreement is contained in Non-Public Appendix I.

H. "Acquisition Date" means the date on which Integra acquires any of the Transferred Assets.

I. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").

J. "Application(s)" means all submissions and applications for a Product filed or to be filed by the holder, the applicant, and/or the sponsor of a Product with the FDA pursuant to 21 C.F.R. Parts 800 to 898 (titled "Regulations Subchapter H—Medical Devices"), including, without limitation, the following:

1. Premarket Notification ("510(k) Submission");

2. Premarket Approval Application ("PMA");

3. Investigational Device Exemption Application ("IDE");

4. Device Master File ("MAF");

5. Device History File ("DHF");

6. Device History Record ("DHR");

7. Device Master Record ("DMR");

8. authorizations to the holder, applicant, and/or sponsor of a Product from any Third Party to incorporate the information contained in an application or submission held by that Third Party to the FDA into a 510(k) Submission, PMA, or IDE submitted or to be submitted by the holder, applicant, and/or sponsor;

9. supplements, amendments, and revisions to the abovementioned submissions and applications;

10. preparatory work, registration dossier, drafts, and data necessary for the preparation of the abovementioned submissions and applications; and

11. all correspondence between the FDA and the holder, the applicant, and/or the sponsor related to the abovementioned submissions and applications.

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c. to the extent known to the specified Respondent, a summary or description of the discussions related to any potential future sales of the Divestiture Product(s) with current or prospective customers; and

d. to the extent known by the specified Respondent, any pending reorder dates for a customer as of the Closing Date;

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4. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

R. "Contract Manufacture" means the following:

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

S. "Contract Manufacture Products" means the following Products, individually and collectively:

1. Intracranial Pressure Monitors;
2. Ventricular Tunnel Catheters;
3. Cerebrospinal Fluid Collection Systems;
4. Non-Antimicrobial External Ventricular Drainage Catheters;
5. Fixed Pressure Valve ShuMCID dy <</MC(m)8(pm)8(pm)8( )-2(i)-2.0LD 11 >>BDCL,a>>B

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

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

BB. "Divestiture Agreement(s)" means the following:

1. Asset Purchase Agreement by and between Integra LifeSciences Holdings Corporation and Natus Medical Incorporated, dated as of September 8, 2017;
2. Integra Shunts Transitional Supply Agreement by and between Integra LifeSciences Holdings Corporation and Natus Medical Incorporated, to be executed on or before the Closing Date;
3. Integra Transitional Services Agreement by and between Integra LifeSciences Holdings Corporation and Natus Medical Incorporated, to be executed on or before the Closing Date;
4. Supply Agreement by and between Integra LifeSciences Holdings Corporation and Natus Medical Incorporated, to be executed on or before the Closing Date;
5. Transition Manufacturing Agreement by and between Integra LifeSciences Holdings Corporation and Natus Medical Incorporated, to be executed on or before the Closing Date;
6. Transition Manufacturing Services Agreement by and between Depuy Synthes, Inc. and Natus Medical Incorporated, to be executed on or before the Closing Date;
7. Transition Services Agreement by and between Depuy Synthes, Inc. and Natus Medical Incorporated, to be executed on or before the Closing Date; and
8. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

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

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

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

EE. "Divestiture Product Core Employees" means Sales and Marketing Employees, Research and Development Employees, and the Manufacturing Employees.

FF. "Divestiture Product License" means a perpetual, non-exclusive, fully paid-up, and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Manufacturing Technology used in the manufacture of the specified Divestiture Product(s) that is also used in the manufacture of Retained Products (i.e., Manufacturing Technology that is used, but not exclusively used in, the manufacture of the Divestiture Product(s) being acquired by a particular Acquirer) that was owned, licensed, held, or controlled by Respondent:

1. to research and Develop the specified Divestiture Product(s) for marketing, distribution, or sale within the United States of America;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Product(s) within the United States of America;
3. to import or export the specified Divestiture Product(s) to or from the United States of America to the extent related to the marketing, distribution, or sale of the specified Divestiture Products in the United States of America; and
4. to have the specified Divestiture Product(s) made anywhere in the world for distribution or sale within, or import into the United States of America;

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

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

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

HH. "Divestiture Trustee

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

JJ. "Dural Graft Product(s)" means all Products researched, Developed, in Development, marketed, sold, owned, or controlled by Johnson & Johnson (prior to the Acquisition) that are a part of, used with, or intended to be used with, the Duraform® product line, listed by device name and 510(k) Number in Non-Public Appendix III.B., and all improvements or modifications thereto.

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

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

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

1. real property at the specified location, including all rights, title, and interests in and to owned or leased land and all improvements thereon, U.S. buildings

VV. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements

6. control history;
7. research and Development records;
8. annual product reviews;
9. supplier lists;
10. labeling and product manuals;
11. manuals and technical information provided to employees, customers, distributors, suppliers, agents, and licensees, including, without limitation, manufacturing, equipment and engineering manuals and drawings;
12. repair and performance records related to the Manufacturing Equipment for the two (2) year period immediately preceding the Closing Date;
13. records related to the protective v(d)1(s)5.1(r)-1(el)41(l)-2ntd [() -(d [() -(e)-1(rhTa2(ad (-(

registrations, licenses, or authorizations granted in connection with any Application related to that Product.

MMM. "Product Contracts" means all contracts or agreements:

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from a Respondent;
2. pursuant to which a Respondent has as of the Closing Date the ability to independently purchase the raw materials, inputs or component(s) from any Third Party, for use in connection with the specified Divestiture Product;
3. relating to any Device Studies involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the specific marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product in finished form in order to provide it to a Respondent;
7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the assembly or packaging of the specified Divestiture Product;
8. pursuant to which a Third Party provides the Manufacturing Technology related to the specified Divestiture Product to a Respondent;
9. pursuant to which a Third Party collaborates with a Respondent in the research and development of any Manufacturing Technology related to the specified Divestiture Product;
10. pursuant to which a Third Party is licensed by a Respondent to use the Manufacturing Technology related to the specified Divestiture Product;
11. constituting confidentiality agreements involving the specified Divestiture Product;
12. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
13. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the specified Divestiture Product to a Respondent including, but not limited to, consultation arrangements;
14. pursuant to which any Third Party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

15. pursuant to which a Respondent leases buildings or equipment that is subject to transfer to the Acquirer pursuant to this Order; and/or

16. pursuant to which a Respondent licenses Software related to the specified Divestiture Product;

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

NNN. "Product Development Reports" means:

1. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from, or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;

2. annual and periodic reports related to the above-described Application(s), including any safety update reports;

3. FDA-approved Product labeling related to the specified Divestiture Product;

4. currently used or planned product package inserts related to the specified Divestiture Product;

5. FDA-approved circulars and information related to the specified Divestiture Product;

6. adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of accuracy related to the specified Divestiture Product;

7. summary of Product complaints from physicians or clinicians related to the specified Divestiture Product;

8. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies, and other documents related to such recalls;

9. investigation reports and other documents related to any out of specification results for any impurities or defects found in the specified Divestiture Product;

10. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including, without limitation, identification and sources of impurities or defects;

11. reports of vendors of the components, active pharmaceutical ingredients, excipients, packaging components,

12. analytical methods development records related to the specified Divestiture Product;

13. manufacturing batch or lot records related to the specified Divestiture Product;

14. stability testing records related to the specified Divestiture Product;

15. change in control history related to the specified Divestiture Product; and

16. executed validation (including design validation and process validation) and qualification protocols and reports related to the specified Divestiture Product.

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

1. a complete and accurate list containing the name of each Divestiture Product Core Employee; and

2. with respect to each such employee, the following information:

   a. the date of hire and effective service date;

   b. job title or position held;

   c. the base salary or current wages;

   d. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, and current target or guaranteed bonus, if any;

   e. employment status (i.e., active or on leave or disability; full-time or part-time); and

3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

PPP. "Product Intellectual Property" means all of the following intellectual property related to a Divestiture Product (other than Product Licensed Intellectual Property) that is owned, licensed, held, or controlled by a Respondent as of the Closing Date:

1. Patents;

2. Copyrights;

3. Software;

4. Trademarks;

5. Trade Dress;

6. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information; and

7. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof, and to bring suit against a Third Party for the past, present, or future

infringement, misappropriation, dilution, misuse, sappr6Tj 03(i)-2(on, m)8(jE2(sa)1n, v)7(i

connection with the Commission's determination to make this Order final and effective;

3. any agreement between a Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including, without limitation, any agreement by that Respondent to supply specified Products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or

4. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of that Respondent related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

TTT. "Research and Development Employees" means all full-time, part-time, and contract employees of a Respondent who have directly participated in the research, Development, regulatory approval process, or Device Studies of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

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

VVV. "Sales and Marketing Employees" means all full-time, part-time, and contract employees of a Respondent whose primary work responsibilities were in the Business of the Divestiture Products within the eighteen (18) month period immediately prior to the Closing Date and who directly have participated in the sales, marketing, or technical support (including installation) of the specified Divestiture Product directly to distributors or end-use cps-c3 Tc 0.003 Tw 18o002 Tc2(e)/ili 0.9(e)a6(di)]TJ 0.009 Tc -0.001Cloif 0 Tdo(re)

YYY. "Technology Transfer Standards" means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (i.e., ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, inter alia:

1. designating employees of a Respondent knowledgeable about the Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Monitor (if one has been appointed), for the purpose of effecting such delivery unless such Persons are hired by the Acquirer;

2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer to the extent that any such technology is either (i) not maintained and fully available at a facility that is being transferred to the Acquirer pursuant to this Order or (ii) not maintained and fully available at a facility operated by the Acquirer's Manufacturing Designee;

3. preparing and implementing a detailed technological transfer plan that contains, inter alia, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee to the extent that any such technology is either (i) not maintained and fully available at a facility that is being transferred to the Acquirer pursuant to this Order or (ii) not maintained and fully available at a facility operated by the Acquirer's Manufacturing Designee

4. permitting employees of the relevant Acquirer to visit the Respondent's facility from which the Divestiture Product will be transferred for the purposes of evaluating and learning the manufacturing process of such Divestiture Product and/or discussing the process with employees of a Respondent involved in the manufacturing process (including, without limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, and validation of the manufacturing of the Divestiture Product at the Respondent's facility)

appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:

   a. the requirements of this Order;

   b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or

   c. applicable Law;

5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Products, (ii) other Persons specifically authorized by that Acquirer to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed) and except to the extent necessary to comply with applicable law;

6. ensure that Confidential Business Information related exclusively to the Divestiture Products is not disseminated among the employees of the Respondents; and

7. after the delivery of the Confidential Business Information to Acquirer of the particular Divestiture Products and upon request of that Acquirer, destroy any copies of Confidential Business Information exclusively related to the particular Divestiture Products acquired by that Acquirer (other than electric copies of Confidential Business Information created as a result of automatic back up procedures) within thirty (30) days of such request except as otherwise agreed to between the Respondents and the Acquirer or to the extent necessary to comply with applicable law;

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

F. Respondents shall provide, or cause to be provided, to the Acquirer in a manner consistent with the Technology Transfer Standards the following:

1. all Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and

2. all rights to all Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to a Respondent related to the Divestiture Product(s) being acquired by that Acquirer.

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

G. Respondents shall, at the option of the Acquirer, and subject to the prior approval of the Commission, provide Transition Services to the Acquirer pursuant to a Transition Services Agreement for a period of (1) year following the Closing Date, with an opportunity to extend for up to one (1) year at the option of the Acquirer; provided, however, that such Agreement shall provide that (1) the Acquirer may terminate the Agreement at any time, without cost or penalty to the Acquirer, upon commercially reasonable notice to Respondents; and (2) at the Acquirer's request, Respondents shall file with the Commission any request for prior approval for any additional extension of the term of a Transition Services Agreement as provided in this Paragraph (i.e., in addition to the initial term plus an extension at the option of the Acquirer). The Transition Services provided pursuant to a Transition Services Agreement shall be at no greater than Respondents' Direct Costs for such personnel, technical support, assistance, training, and other services as are necessary to transfer the Divestiture Product Assets to the Acquirer in a manner consistent with the purposes of this Order.

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cGMP, independently of the supplying Respondent; (ii) the date the Acquirer notifies the Commission and the supplying Respondent of its intention to abandon its efforts to manufacture the relevant Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the relevant Contract Manufacture Product; or, for any Contract Manufacturing Product, excluding Crainial Access Kits, (iv) five (5) years after the Closing Date.

J. Respondents shall designate employees of Respondents knowledgeable about the marketing, distribution, warehousing, and sale (including administrative logistics of sales to the respective High Volume Accounts) related to each of the Divestiture Products to

1. for a period of twelve (12) months after the Closing Date, provide the Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and Divestiture Product Assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s);"

2. not later than the earlier of the following dates: (i) ten (10) days after requested by staff of the Commission to the relevant Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer or Proposed Acquirer(s) provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by that Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; provided, however, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, (ii) use the information solely in connection with considering whether to provide, or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use;

3. during the Divestiture Product Core Employee Access Period(s), not interfere with

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

requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.

3. The Monitor shall serve until the latter of:

   a. the date the Respondents complete the transfer of all Divestiture Product Assets, and the transfer and delivery of the related Manufacturing Technology, Product Intellectual Property, and Product Licensed Intellectual Property;

   b. the date that each respective Acquirer has obtained all Product Approvals necessary to manufacture and market each Divestiture Product acquired by that Acquirer in the United States of America independently of the Respondents; or

   c. the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned

claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.

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

G. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; provided, however, that such agreement shall not restrict the Monitor from providing any information to the Commission.

H. 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.

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satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the

B. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

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

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

VI.

IT IS FURTHER ORDERED that:

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

B. Any failure by

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 Date, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition Date occurred.

B. Within five (5) days of each Closing Date, Respondents shall submit to the Commission a letter certifying the date on which that particular divestiture occurred.

C. Within thirty (30) days after the Order Date, and every ninety (90) days thereafter until Respondents have (i) transferred all of the Divestiture Assets to the relevant Acquirer(s), and (ii) fully provided th

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

IX.

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

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

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

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

C. with respect to any Product Licensed Intellectual Property, Johnson & Johnson has granted or otherwise provided the rights to use such intellectual property either directly to

NON-PUBLIC APPENDIX I
ACQUISITION AGREEMENT

NON-PUBLIC APPENDIX II
DIVESTITURE AGREEMENTS

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

NON-PUBLIC APPENDIX III
DIVESTITURE PRODUCTS

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

NON-PUBLIC APPENDIX III.B.
DURAL GRAFT PRODUCTS

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

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

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

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

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

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

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

NON-PUBLIC APPENDIX III.F.

FIXED PRESSURE VALVE SHUNT SYSTEMS EQUIPMENT

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

APPENDIX IV
CRANIAL ACCESS KITS

[Cover Page; Add Public Material]

APPENDIX V
MONITOR AGREEMENT

NON-PUBLIC APPENDIX V.A

MONITOR AGREEMENT