



**[BILLING CODE: 6750-01S]**

**FEDERAL TRADE COMMISSION**

**[File No. 171 0084]**

**Integra LifeSciences Holdings Corporation and Johnson & Johnson; Analysis to Aid Public Comment**

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed Consent Agreement.

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**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders -- embodied in the consent agreement -- that would settle these allegations.

**DATES:** Comments must be received on or before October 27, 2017.

**ADDRESSES:** Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: "Integra LifeSciences et al.; FTC File No. 1710084" on your comment, and file your comment online at <https://ftcpublishcommentworks.com/ftc/integradivest> by following the instructions on the web-based form. If you prefer to file your comment on paper, write "Integra LifeSciences et al.; FTC File No. 1710084" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D),

Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** Aylin M. Skroejer, (202-326-2459), Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR § 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for September 27, 2017), on the World Wide Web, at <https://www.ftc.gov/news-events/commission-actions>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 27, 2017. Write “Integra LifeSciences et al.; FTC File No. 1710084” on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at <https://www.ftc.gov/policy/public-comments>.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/integradivest> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#!home>, you also may file a comment through that website.

If you prefer to file your comment on paper, write “Integra LifeSciences et al.; FTC File No. 1710084” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC. 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC Website at <https://www.ftc.gov>, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else’s Social Security number; date of birth; driver’s license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential” – as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2) – including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must

include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC Website – as legally required by FTC Rule 4.9(b) – we cannot redact or remove your comment from the FTC Website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC Website at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 27, 2017. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

## **Analysis of Agreement Containing Consent Orders to Aid Public Comment**

### **INTRODUCTION**

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

non-antimicrobial external ventricular drainage catheters, and dural grafts.

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

Under the terms of the Asset Purchase Agreement signed on February 14, 2017, Integra will acquire Codman in a transaction valued at approximately \$1.0 billion (the “Acquisition”). The Commission’s Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in the U.S. markets for intracranial pressure monitoring systems, cerebrospinal fluid collection systems, non-antimicrobial external ventricular drainage catheters, fixed pressure valve shunt systems, and dural grafts. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in these markets as a result of the proposed Acquisition.

## **THE PARTIES**

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

Codman, part of Johnson & Johnson’s DePuy Synthes Inc. business unit, is a global

medical device company that offers a diverse portfolio of neurosurgery, neurovascular, and drug delivery products, including instruments and systems for hydrocephalus management, neurointensive care, and cranial surgery, as well as implantable drug infusion systems. The proposed transaction excludes Codman's neurovascular and drug delivery businesses.

## **THE RELEVANT PRODUCTS AND STRUCTURE OF THE MARKETS**

### **I. Intracranial Pressure Monitoring Systems**

Intracranial pressure monitoring systems are used in intensive care units and operating rooms to measure pressure inside the skull, which can increase in the event of traumatic brain injury, hydrocephalus, intracranial tumors, and other medical conditions. An increase in intracranial pressure can severely damage the brain or spinal cord and is a common cause of death in neurosurgical patients, making quick detection of pressure buildup critical. Intracranial pressure monitoring systems use a pressure-sensitive probe inserted through the skull to send measurements via a transducer cable to a monitor at the patient's bedside. Customers would not switch to an alternative product in response to a small but significant increase in the price of intracranial pressure monitoring systems.

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

### **II. Cerebrospinal Fluid Collection Systems**

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

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

### **III. Non-Antimicrobial External Ventricular Drainage Catheters**

External ventricular drainage catheters funnel excess cerebrospinal fluid from the brain to cerebrospinal fluid collection systems to relieve intracranial pressure. External ventricular drainage catheters are either antimicrobial or non-antimicrobial, and the two types constitute distinct antitrust markets because of the substantial differences between them. Non-antimicrobial external ventricular drainage catheters lack an antibiotic coating and are suitable for less critical patients; they also may be used to avoid the risk of antibiotic interference when diagnosing infections. They are significantly less expensive than antimicrobial external ventricular drainage catheters. Customers would not switch from non-antimicrobial external ventricular drainage catheters to the antimicrobial versions or any other product in response to a 5% to 10% increase in the price of non-antimicrobial external ventricular drainage catheters, in part because even with such a price increase, antimicrobial external ventricular drainage catheters would still be considerably more expensive.

Integra and Codman account for 29% and 17% of the relevant market in the United

States. The only other competitively significant firm is Medtronic, with a 51% share.

#### **IV. Fixed Pressure Valve Shunt Systems**

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

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

Integra, Codman, and Medtronic are the only significant suppliers of fixed pressure valve shunt systems. Medtronic accounts for 55% of U.S. sales, and Integra follows at 23% share and Codman at 15% share. Aesculap and Sophysa hold small, fringe positions in the market and their products are not close substitutes to those of Integra and Codman.

#### **V. Dural Grafts**

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

### **THE RELEVANT GEOGRAPHIC MARKET**

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

### **COMPETITIVE EFFECTS OF THE ACQUISITION**

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

## **ENTRY CONDITIONS**

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

## **THE CONSENT AGREEMENT**

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

ensure that Natus becomes an independent, viable, and effective competitor in the respective U.S. markets in order to maintain the competition that currently exists.

Based in Pleasanton, California, Natus is a global healthcare company that provides screening, diagnostic, and monitoring solutions for its three business units: neurology, newborn care, and hearing and balance care. Its neurology business includes systems that are highly complementary to the divestiture assets and test for a variety of medical conditions, including epilepsy, head injury, tumors, Parkinson's, and sleep apnea. Natus is well positioned to restore the competition that otherwise would have been lost pursuant to the proposed Acquisition.

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

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

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

By direction of the Commission.

Donald S. Clark,  
Secretary.

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