

be filed pursuant to section 241.3(b)(3)(i) is covered in specific memoranda relating to those forms. With respect to the "Registration of a Securities Holding Company" form required pursuant to section 241.3(a)(1), the information submitted on and with the form is normally public. However, a company may seek confidential treatment for any such information that it believes is exempt from disclosure under FOIA (5 U.S.C. 552(b)(1)–(9)). A determination of confidentiality would be made on a case-by-case basis.

**Abstract:** On June 4, 2012, the Federal Reserve published a final rulemaking for Securities Holding Companies (Regulation OO) in the **Federal Register** (77 FR 32881). Regulation OO implements section 618 of the Dodd-Frank Act, which permits nonbank companies that own at least one registered securities broker or dealer, and that are required by a foreign regulator or provision of foreign law to be subject to comprehensive consolidated supervision, to register with the Board and subject themselves to supervision by the Board.

**Current Actions:** On July 23, 2015, the Federal Reserve published a notice in the **Federal Register** (80 FR 43777) requesting public comment on the proposed extension, without revision, of the FR 2082. The comment period for the notice expired on September 21, 2015. The Federal Reserve did not receive any comments on the proposal, and the FR 2082 will be extended without revision as proposed.

Final approval under OMB delegated authority of the extension, with revision, of the following report:

**Report title:** Request for Proposal and Request for Price Quotations.

**Agency form number:** RFP and RFPQ.

**OMB control number:** 7100–0180.

**Frequency:** On occasion.

**Reporters:** Vendors of goods and services.

**Estimated annual reporting hours:**

RFP: 17,500 hours; RFPQ: 4,400 hours; Subcontractor report: 50 hours.

**Estimated average hours per response:** RFP: 50 hours; RFPQ: 2 hours; Subcontractor report: 20 minutes.

**Number of respondents:** RFP: 350; RFPQ: 2,200; Subcontractor report: 150.

**General description of report:** The RFP and RFPQ are required to obtain a benefit and are authorized by Sections 10(3), 10(4), and 11(1) of the Federal Reserve Act (12 U.S.C. 243, 244, and 248(l)). With regard to the Subcontracting Report, Section 342(c) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) requires the Federal Reserve to develop and implement standards and

procedures to assess the diversity policies and practices in all business and activities of the agency at all levels, including procurement, insurance, and all types of contracts. (12 U.S.C. 5452(c)(1)). "Such procedure shall include a written statement, in a form and with such content as the Director [of OMWI] shall prescribe . . . that a contractor shall ensure . . . the fair inclusion of women and minorities in the workforce of the contractor and, as applicable, subcontractors." (12 U.S.C. 5452(c)(2)).

Proposals from vendors that are not accepted and incorporated into contracts with the Federal Reserve would be protected from Freedom of Information (FOIA) disclosure by 41 U.S.C. 4702, which expressly prohibits FOIA disclosure of these proposals. Moreover, during the solicitation process vendors are permitted to mark information contained in their proposals that is proprietary or confidential with the label RESTRICTED DATA. For information so marked, the Federal Reserve also may determine on a case-by-case basis whether FOIA exemption 4, which applies to "trade secrets and commercial or financial information," would protect information from disclosure pursuant to a FOIA request (5 U.S.C. 552(b)(4)).

**Abstract:** The Federal Reserve uses the RFP and the RFPQ as appropriate to obtain competitive proposals and contracts from approved vendors of goods and services. This information collection is required to collect data on prices, specifications of goods and services, and qualifications of prospective vendors.

**Current Actions:** On July 23, 2015, the Federal Reserve published a notice in the **Federal Register** (80 FR 43777) requesting public comment on the proposed extension, with revision, of the RFP and RFPQ. In connection with the RFP and RFPQ process, the Federal Reserve proposed to require prime contractors to submit a Subcontracting Report that would collect information about their subcontractors' commitments toward diversity and inclusion of minority-owned and women-owned vendors in the subcontractor's activities. The comment period for the notice expired on September 21, 2015. The Federal Reserve received one comment, which stated that contracting programs should be open to all and that no one should be discriminated against nor granted preferential treatment because of skin color, national origin, or sex. The RFP and RFPQ will be extended with revision as proposed.

Board of Governors of the Federal Reserve System, October 5, 2015.

**Robert deV. Frierson,**  
Secretary of the Board.

[FR Doc. 2015–25664 Filed 10–7–15; 8:45 am]

**BILLING CODE 6210–01–P**

## FEDERAL TRADE COMMISSION

[File No. 151 0018]

### Wright Medical Group, Inc. and Tornier N.V.; Analysis To Aid Public Comment

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed consent agreement.

**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 draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

**DATES:** Comments must be received on or before October 30, 2015.

**ADDRESSES:** Interested parties may file a comment at <https://ftcpublic.commentworks.com/ftc/wrighttornierconsent> online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Wright Medical Group, Inc. and Tornier N.V.—Consent Agreement; File No. 151 0018" on your comment and file your comment online at <https://ftcpublic.commentworks.com/ftc/wrighttornierconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write "Wright Medical Group, Inc. and Tornier N.V.—Consent Agreement; File No. 151 0018" 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. Skroeger (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 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 30, 2015), on the World Wide Web, at <http://www.ftc.gov/os/actions.shtm>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 30, 2015. Write "Wright Medical Group, Inc. and Tornier N.V.—Consent Agreement; File No. 151 0018" 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 Web site, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone'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, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in 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). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).<sup>1</sup> Your comment will be kept

confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

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/wrighttornierconsent> 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 Web site.

If you file your comment on paper, write "Wright Medical Group, Inc. and Tornier N.V.—Consent Agreement; File No. 151 0018" 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.

Visit the Commission Web site 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 30, 2015. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

### **Analysis of Agreement Containing Consent Order To Aid Public Comment Introduction**

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Order ("Consent Agreement") from Wright Medical Group, Inc. ("Wright") and Tornier N.V. ("Tornier") designed to remedy the anticompetitive effects resulting from the proposed merger of Wright and Tornier. Under the terms of the proposed Decision and Order ("Order")

contained in the Consent Agreement, the parties are required to divest to Integra Lifesciences Corporation ("Integra") all of Tornier's rights and assets related to the following reconstructive joint markets: (1) Total ankle replacements; (2) total silastic big toe joint replacements; and (3) total silastic toe joint replacements for the second through fifth "lesser" toes.

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 again review the Consent Agreement and the comments received, and decide whether it should withdraw from the Consent Agreement, modify it, or make it final.

Pursuant to an Agreement and Plan of Merger dated October 27, 2014, Wright and Tornier propose to merge in an all-stock transaction valued at approximately \$3.3 billion (the "Proposed Merger"). The Commission's Complaint alleges that the Proposed Merger, 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 total ankle replacements and total silastic toe joint replacements. 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 Merger.

### **The Parties**

Headquartered in Memphis, Tennessee, Wright is a global orthopedic company that divides its business into three categories: foot and ankle hardware; upper extremity reconstructive devices; and biologics products.

Tornier is a global medical device company based in Amsterdam, the Netherlands, with U.S. operations headquartered in Bloomington, Minnesota. Tornier's U.S. products include those for the upper extremity joints; lower extremity joints; sports medicine; and biologics.

### **The Relevant Products and Structure of the Markets**

#### **I. Total Ankle Replacements**

Total ankle replacements are used to treat end-stage ankle arthritis, which develops when cartilage on the bones of the ankle joint wears away and causes bone-on-bone grinding down of the joint

<sup>1</sup> 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), 16 CFR 4.9(c).

surface. Patients with end-stage ankle arthritis experience pain and swelling at the ankle along with difficulty walking. Total ankle replacements reduce the pain while maintaining the motion at the ankle joint. They replace damaged bone and cartilage with a metal tibial tray, a metal talar dome, and a polyethylene bearing. In a fixed bearing total ankle replacement, the polyethylene bearing is locked to the tibial component, while in a mobile bearing system it moves independently. Physicians and their patients would not switch to an alternative product or therapy in response to a small but significant increase in the price of total ankle replacements.

Wright, Tornier, and Stryker Corporation (“Stryker”) are the only significant suppliers in the U.S. market for total ankle replacements, accounting for 44%, 19%, and 31% of 2014 sales, respectively. Wright and Tornier are each other’s closest competitor. These companies both offer fixed bearing technologies and the only options for revision surgeries, *i.e.*, surgeries to redo a prior total ankle replacement procedure. The other leading supplier, Stryker, supplies the only mobile bearing system in the United States, making it a more distant competitor to Wright and Tornier. The only other U.S. supplier of total ankle replacements, Zimmer Holdings, Inc. (“Zimmer”) offers a technology that typically is used only in specialized cases. Zimmer maintains a fringe position in the market.

## II. Total Silastic Toe Joint Replacements

Total big toe joint replacements treat severe cases of *hallux rigidus*, an arthritic condition in the first metatarsophalangeal (“MTP”) joint of the big toe. Pain and inflammation at the first MTP joint restricts movement of the big toe and leads to difficulty walking. Total big toe joint replacements relieve pain and preserve motion in the big toe.

There are two types of total big toe joint replacements: Metal and silastic. Total silastic big toe joint replacements are a distinct antitrust market. Surgeons that favor total silastic big toe joint replacements over metal implants do so for the silastic implants’ flexibility and longevity. The silastic implants are also significantly less expensive than total metal big toe joint replacements. Physicians and patients do not view total silastic and total metal big toe joint replacements as reasonably interchangeable. A small but significant increase in the price of total silastic big toe joint replacements would not cause

physicians or patients to switch to other products or therapies.

The U.S. market for total silastic big toe joint replacements is highly concentrated. Wright and Tornier are the only significant suppliers of the product, accounting for approximately 60% and 38% of the market, respectively. The next closest competitor to Wright and Tornier—Sgarlato Med LLC—accounts for a nominal share of the market.

Although more rare than in the big toes, severe arthritis also occurs in the MTP joints of the lesser toes. Physicians and patients who use total silastic lesser toe joint replacements would not switch to any other product or procedure in response to a small but significant increase in the price of the total silastic toe joint implants. Wright, Tornier, and OsteoMed supply total silastic lesser toe joint replacements in the United States, and Wright and Tornier are each other’s closest competitor. The Proposed Merger would result in a combined market share of approximately 76%.

The relevant geographic market for total ankle replacements and total silastic toe joint replacements is the United States. 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.

### 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 Merger. To enter or effectively expand in any of the relevant markets successfully, a supplier would need to design and manufacture an effective product, obtain FDA approval, and develop clinical history supporting the long-term efficacy of its product. The new entrant or expanding firm would also need to develop and foster product loyalty and establish a nationwide sales network capable of marketing the product and providing on-site service at hospitals nationwide. Establishing a track record for quality, service, and consistency is difficult, expensive, and typically spans several years.

### Competitive Effects of the Merger

The Proposed Merger would likely result in significant competitive harm to consumers in the markets for total ankle replacements and total silastic toe joint replacements. As particularly close substitutes in each relevant market,

Wright and Tornier respond directly to competition from each other with improved products, better service, and lower prices. By eliminating this direct and substantial head-to-head competition, the Proposed Merger likely would allow the combined firm to exercise market power unilaterally, resulting in less innovation and higher prices for consumers.

### The Consent Agreement

The Consent Agreement eliminates the competitive concerns raised by the Proposed Merger by requiring the parties to divest to Integra all of the rights and assets needed for it to become an independent, viable, and effective competitor in the U.S. markets for total ankle replacements and total silastic toe joint replacements. The divestitures will maintain the competition that currently exists in each of the relevant markets.

Integra is well positioned to restore the competition that otherwise would be lost through the Proposed Merger. Headquartered in Plainsboro, New Jersey, Integra is a global medical device company that has experience manufacturing, marketing, and distributing orthopedic devices in the United States, and a track record for quality, service, and consistency. Integra’s lower extremity product portfolio is also highly complementary to Tornier’s total ankle replacements and total silastic toe joint replacements.

The Order requires Tornier to divest all U.S. assets and rights related to the relevant products, including intellectual property, manufacturing technology, and existing inventory. In order to ensure continuity of supply, the Order requires that the parties supply Integra with total ankle replacements for up to three years and total silastic toe joint replacements for up to one year while Integra transitions to independent manufacturing and works to obtain FDA approval.

To ensure that the divestitures are successful, the Order requires the parties to enter into a transitional services agreement with Integra to assist the company in establishing its manufacturing capabilities and securing all necessary FDA approvals. Further, the Order requires that the parties transfer all confidential business information to Integra, as well as provide access to employees who possess or are able to identify such information. Integra also will have the right to interview and offer employment to employees associated with the relevant products.

The parties must accomplish these divestitures and relinquish their rights to Integra no later than ten days after the

Proposed Merger is consummated. If the Commission determines that Integra 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 Integra and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The Order also requires the parties to appoint Quantic Regulatory Services, LLC as interim monitor to ensure the parties comply with the obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the assets and rights to Integra.

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.*

[FR Doc. 2015-25604 Filed 10-7-15; 8:45 am]

BILLING CODE 6750-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-16-15BHD; Docket No. CDC-2016-0088]

#### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Congenital Heart Surveillance to Recognize Outcomes, Needs and well-being (CHSTRONG). CDC seeks to collect data for the purpose of providing insight into the public health questions that remain for

the population and to develop services and allocate resources to improve long-term health and wellbeing.

**DATES:** Written comments must be received on or before December 7, 2015.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2016-0088 by any of the following methods:

- *Federal eRulemaking Portal:*

*Regulation.gov.* Follow the instructions for submitting comments.

- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the

use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

#### Proposed Project

Congenital Heart Surveillance To Recognize Outcomes, Needs, and Well-being (CHSTRONG)—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Congenital heart defects (CHDs) are the most common type of structural birth defects, affecting approximately 1 in 110 live-born children. In prior decades, many CHDs were considered fatal during infancy or childhood, but with tremendous advances in pediatric cardiology and cardiac surgery, at least 85% of patients now survive to adulthood and there are approximately 1.5 million adults with CHD living in the United States. With vast declines in mortality from pediatric heart disease over the past 30 years, it is vital to evaluate long term outcomes and quality of life issues for adults with CHD. However, U.S. data on long term outcomes, quality of life issues, and comorbidities of adults born with CHD are lacking. U.S. data is needed to provide insight into the public health questions that remain for this population and to develop services and allocate resources to improve long-term health and wellbeing.

For this one-year project, we will use data from U.S. state birth defect surveillance systems to identify a population-based sample of individuals 18 to 45 years of age born with CHD. We will then use state databases and online search engines to find current addresses for those individuals and mail surveys to them inquiring about their barriers to