[BILLING CODE: 6750-01S]

FEDERAL TRADE COMMISSION

[File No. 191 0039]

Boston Scientific Corporation; Analysis of Agreement Containing Consent Orders to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement; Request for Comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis of Agreement Containing Consent Orders 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: "Boston Scientific Corporation; File No. 191 0039" on your comment, and file your comment online at https://www.regulations.gov by following the instructions on the web-based form. If you prefer to file your comment on paper, 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: Jonathan Ripa (202-326-2230), Bureau of Competition, Federal Trade Commission, 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 August 7, 2019), 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]. Write "Boston Scientific Corporation; File No. 191 0039" 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 https://www.regulations.gov website.

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 through the https://www.regulations.gov website.

If you prefer to file your comment on paper, write "Boston Scientific Corporation; File No. 191 0039" 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 website at https://www.regulations.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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]. 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

I. Introduction

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Boston

Scientific Corporation ("BSC") designed to remedy the anticompetitive effects resulting from BSC's proposed acquisition of BTG plc ("BTG"). The proposed Decision and Order ("Order") contained in the Consent Agreement requires BSC to divest all rights and assets related to its drug eluting bead ("DEB") business, as well as its closely related bland bead business, to Varian Medical Systems ("Varian").

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 Co-Operation Agreement dated November 20, 2018, BSC will acquire BTG in exchange for cash consideration of $4.2 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. market for DEBs. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in this market as a result of the proposed Acquisition.

II. The Parties

BSC, headquartered in Marlborough, Massachusetts, is a global supplier of medical devices that are used in a broad range of interventional medical specialties. BSC currently offers its products through seven core business segments: Interventional Cardiology, Cardiac Rhythm Management, Endoscopy, Peripheral Interventions, Urology

and Pelvic Health, Neuromodulation, and Electrophysiology. The Peripheral Interventions segment—which includes BSCs DEB business—focuses on products that treat an array of diseases, including arterial diseases, vascular diseases, as well as various cancers.

BTG is headquartered in London, England, with operational headquarters in Conshohocken, Pennsylvania. The company develops, manufacturers, and sells products used in various interventional medicine applications, and it also has a portfolio of specialty pharmaceutical products.

III. The Relevant Product and Structure of the Market

DEBs are microscopic beads used in transarterial chemoembolization ("TACE") procedures for treating primary and secondary liver cancers. TACE involves the use of embolic agents (typically microscopic beads) mixed with chemotherapy drugs (often doxorubicin) that are delivered to the targeted tumor in the liver via a catheter inserted into the patient's artery that leads to the tumor. When used in TACE procedures, DEBs work by blocking the flow of blood to the liver tumor, causing it to shrink over time, while simultaneously slowly releasing a chemotherapy agent that also attacks the tumor.

BTG and BSC are the two leading suppliers of DEBs in the United States and are each other's closest competitors. The only other participant in the U.S. DEB market is Merit Medical ("Merit"), which is substantially smaller than either BSC or BTG.

IV. The Relevant Geographic Market

The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition. DEBs are medical devices that are regulated by the U.S. Food and Drug Administration ("FDA"). As such, DEBs sold

outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

V. Competitive Effects of the Acquisition

The proposed Acquisition would likely result in substantial competitive harm to consumers in the market for DEBs. The parties are two of only three significant suppliers of DEBs in the United States. Eliminating the head-to-head competition between BSC and BTG in this highly concentrated market would allow the combined firm to exercise market power unilaterally, resulting in higher prices, reduced innovation, and less choice for consumers.

VI. Entry Conditions

Entry in the relevant market 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 for product research and development, regulatory approval by the FDA, developing clinical history supporting the long-term efficacy of the product, and establishing a U.S. sales and service infrastructure. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market.

VII. The Consent Agreement

The Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by requiring BSC to divest its DEB business and closely related bland bead business to Varian. A sale of BSC's DEB business without its bland business could undermine the divestiture's effectiveness. The two products share key intellectual

property, and BSC manufactures bland beads on the same production line as DEBs. Thus, including the bland bead business in the divestiture package will ensure that Varian has outright ownership of all necessary intellectual property and allow it to manufacture DEBs at a cost and output level comparable to that of BSC. BSC must divest all assets and rights to research, develop, manufacture, market, and sell the BSC DEB and bland bead products, including all related intellectual property and other confidential business information, manufacturing technology, existing inventory, and all related agreements to manufacture and distribute the products. Additionally, to ensure that the divestiture is successful and maintain continuity of supply, the proposed Order requires BSC to supply Varian with DEBs and bland beads for a limited time while Varian establishes its own manufacturing capability. The provisions of the Consent Agreement ensure that Varian becomes an independent, viable, and effective competitor in the U.S. market in order to maintain the competition that currently exists.

Headquartered in Palo Alto, California, Varian operates globally and develops, manufactures, and markets a variety of medical devices and software for treating cancer and other medical conditions. Varian's existing interventional oncology business includes products that are highly complementary to the divestiture assets. Varian has the expertise, U.S. sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the proposed Acquisition.

BSC must accomplish the divestitures no later than ten days after consummating the proposed Acquisition. If the Commission determines that Varian is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires BSC to unwind the sale of rights and assets to Varian and then divest the

affected products to a Commission-approved acquirer 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 BSC complies with all of its obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the DEB and bland bead rights and assets to Varian. The proposed Order further allows the Commission to appoint a trustee in the event that BSC fails 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.

April J. Tabor,

Acting Secretary.

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