December 20, 2021

Boston Scientific Corporation
Anuja Bhatt
Senior Regulatory Affairs Specialist
300 Boston Scientific Way
Marlborough, MA 01752

Re: K211847
Trade/Device Name: AdVance™ XP Male Sling System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTM
Dated: November 19, 2021
Received: November 23, 2021

Dear Anuja Bhatt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number: K211847

Device Name
AdVance™ XP Male Sling System

Indications for Use *(Describe)*
The AdVance™ XP Male Sling System is intended for the treatment of male stress urinary incontinence (SUI) by the placement of a suburethral sling.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

SUBMITTER

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Contact Person: Anuja Bhatt, Senior Regulatory Affairs Specialist
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Date Prepared: June 14, 2021

DEVICE

Trade Name: AdVance™ XP Male Sling System
Model Number: 720163-03
Regulatory Class: II
Product Code: OTM
Product Code Name: Mesh, Surgical, For Stress Urinary Incontinence, Male
Common/Usual/Classification Name: Surgical Mesh
Classification Number: 21 CFR 878.3300

PREDICATE DEVICE

Trade Name: AdVance™ XP Male Sling System, 510(k) K182169 (cleared November 27, 2018)
Model Number: 720163-01
Regulatory Class: II
Product Code: OTM
Product Code Name: Mesh, Surgical, For Stress Urinary Incontinence, Male
Common/Usual/Classification Name: Surgical Mesh
Classification Number: 21 CFR 878.3300
Sponsor: Boston Scientific Corporation

REFERENCE DEVICE

Trade Name: Obtryx™ II System, 510(k) K121754 (cleared October 10, 2012)
Regulatory Class: II
Product Code: OTN
Product Code Name: Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator
Common/Usual/Classification Name: Surgical Mesh
Classification Number: 21 CFR 878.3300
Sponsor: Boston Scientific Corporation

ENVIRONMENT OF USE

Healthcare facility/Hospital

DEVICE DESCRIPTION

AdVance™ XP Male Sling System is a sling system which treats male stress urinary incontinence by repositioning the urethra with a suburethral mesh. The AdVance XP Male Sling System is comprised of a permanently implanted monofilament polypropylene mesh sling, two needle passers used to implant the sling, and retraction system (retractor ring and stay hooks). The male sling is connected during the procedure to the needle passers through keyed connectors at each end of the male sling which are removed after the male sling is positioned. The male sling repositions the bulbar urethra 2-4cms. The AdVance™ XP Male Sling System kit is composed of four primary components: Male Sling, Needle Passers, Retractor Ring, and Stay Hooks. The AdVance™ XP Male Sling and Needle Passers are the subject of this submission. The Retraction System (retractor ring and stay hooks) is purchased pre-sterilized off the shelf components and is cleared through K791665.

INDICATIONS FOR USE

The AdVance™ XP Male Sling System is intended for the treatment of male stress urinary incontinence (SUI) by the placement of a suburethral sling.

The indications for use of the AdVance™ XP Male Sling System are the same as the predicate device (K182169).

OPERATING PRINCIPLE

AdVance™ XP Male Sling System and the predicate device (K182169) achieve their mechanism of action by repositioning the bulbar urethra 2-4 cm.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

AdVance™ XP Male Sling System and the predicate device (K182169) have the same intended use, device material, design, environment of use (healthcare facility/hospital), mesh material, pore size, sling arm width, sheath and connectors, sterilization method (Ethylene

Oxide), Needle Passers, placement route (transobturator), procedural steps, similar design and fundamental technology of mesh assemblies.

The primary differences between AdVance™ XP Male Sling System and the predicate device (K182169) are the Ethylene Oxide sterilization cycle, sterilization sites, packaging configuration and materials, shelf life, and kitting location.

SUBSTANTIAL EQUIVALENCE

A direct comparison of key characteristics demonstrates that the AdVance™ XP Male Sling System is substantially equivalent to the predicate device (K182169) in terms of intended use, technological and performance characteristics.

STERILITY

The predicate device (K182169) and proposed AdVance™ XP Male Sling System utilize the same sterilization method (Ethylene Oxide) but different sterilization parameters and sterilization locations. The AdVance™ XP Male Sling System has been qualified to be used with the different sterilization parameters. Ethylene Oxide residual testing was successfully completed on the AdVance™ XP Male Sling System device. The device has met the **ISO 10993-7:2008** requirements for the respective classification after 0 days, 0 hours of aeration following 1X and 2X exposures in the sterilization cycle. This device categorized as Limited Contact/Implantable meets the TCL limits as per ISO 10993-7:2008. The AdVance™ XP Male Sling System is sterilized to a Sterility Assurance Level (SAL) of 10^{-6}.

BIOCOMPATIBILITY

A biological evaluation was performed within a risk management process using the framework established in **ISO 10993-1: 2018** and Section III of the FDA guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical device- Part 1: Evaluation and testing within a risk management process."* to demonstrate the proposed AdVance™ XP Male Sling System is biocompatible for its intended use. This biological evaluation included the materials of the device, processing of the materials, manufacturing methods (inclusive of sterilization), and potential residuals from manufacturing processing aids. In assessing the changes to the AdVance™ XP Male Sling System and consideration of testing to mitigate potential biocompatibility risks, the clinical use, anatomical location, duration of exposure, and intended patient population were all taken into consideration. The packaging and sterilization modifications that are the subject of this submission did not affect the materials of the device or the fact that it is biocompatible for its intended use. Therefore, existing testing of the predicate device and reference device demonstrate the biological safety of the subject AdVance™ XP Male Sling System device.

PERFORMANCE DATA

Performance testing was conducted on non-aged samples and samples that were accelerated aged for the equivalent of 37 months, in order to support a 3-year shelf life. To demonstrate substantial equivalence of the AdVance™ XP Male Sling System to the predicate device (K182169), technological characteristics and performance criteria were evaluated using bench testing, sterilization evaluation, and shelf life testing. The following performance tests were completed:

- Design verification and validation
- Packaging tests
- Shelf life assessments
- Sterility assurance

The results of performance testing demonstrate that the technological characteristics and performance criteria of the AdVance™ XP Male Sling System are comparable to the predicate device (K182169) and functions as intended equivalent to devices currently on the market for the same intended use.

CONCLUSION

Based on the indication for use, technological characteristics, and performance data it can be concluded that the AdVance™ XP Male Sling System is substantially equivalent to the predicate device (K182169) and is appropriate for the indications for use