November 15, 2024

Boston Scientific Corporation
Natalie Asprey
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K242960
Trade/Device Name: AdVance™ XP Male Sling System (720163-03)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTM
Dated: September 25, 2024
Received: September 25, 2024

Dear Natalie Asprey:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242960

Device Name

AdVance™ XP Male Sling System (720163-03)

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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Urology
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510(k) Summary

Submitter

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USA

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Date Prepared: 25 September 2024

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Proposed Device K242960

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 K211847

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
Manufacturer: Boston Scientific Corporation

Device Description

The AdVance XP Male Sling System is provided as a sterile, single-use, single-pack kit composed of the following primary components: Male Sling, Needle Passers (2), Retractor Ring, and Stay Hooks. The subject of this premarket notification is around the Male Sling component of the AdVance XP Male Sling System, specifically the implantable portion of the Male Sling assembly, which is the mesh sling and the tissue anchors. There are no modifications to the Needle Passers, or Retractor Ring and Stay Hooks (which form the Retraction System) as a part of this submission. Note that the Retraction System are comprised of purchased, off-the-shelf components cleared through K791665.

Environment of Use

Healthcare facility/Hospital

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.

Operating Principle

The AdVance XP Male Sling is a suburethral mesh implant designed to treat male incontinence by repositioning the urethra. AdVance XP needle passers assist in the placement of the male sling. AdVance XP Male Sling System is an implanted, surgical device that penetrates inside the body. Its intended purpose is for the treatment of male stress urinary incontinence (SUI) by the placement of a suburethral sling.

Comparison of Technological Characteristics with the Predicate Device

The proposed AdVance XP Male Sling System and the predicate device (K211847) have identical indications for use, operating principle, finished good device dimensions and features, environment of use, sterilization method, shelf life, Needle Passers, and Retraction System.

The primary differences between the proposed AdVance XP Male Sling System and the predicate device (K211847) are the material composition and the material wash process (including processing aids).

Substantial Equivalence

The direct comparison of key characteristics, along with data presented in this premarket notification, demonstrates that the proposed AdVance XP Male Sling System is substantially equivalent to the predicate AdVance XP Male Sling System device, which was cleared by the FDA under premarket notification K211847.

Sterility

There were no changes in the sterilization process used for the AdVance XP Male Sling System, however an ethylene oxide (EO) sterilization qualification was performed to confirm that the proposed device continues to meet a SAL of 10-6 or better and in accordance with global BSC procedures and ISO 11135. Additionally, a microbiology evaluation was performed in accordance

with global BSC procedures, ISO 11737-1, and ANSI AAMI ST72 to ensure the proposed device continues to meet bioburden and endotoxin requirements.

Biocompatibility

A biological evaluation was performed per ISO 10993-1 *Biological Evaluation of Medical Devices – Part 1* and FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* to demonstrate that the proposed AdVance XP Male Sling System device is biocompatible for its intended use. This biological evaluation included assessment of the materials of construction (including processing of the materials and processing aids), toxicological risk assessment, and biological testing.

Results of the material characterization, toxicological risk assessment, and biological testing support the biocompatibility of the device. The biological evaluation conducted in accordance with ISO 10993-1 and FDA Guidance (2023) confirms that the AdVance XP Male Sling System is biocompatible for its intended use per its ISO 10993-1 categorization as a Implant, Tissue/Bone, Permanent (> 30 day) contact device. The results of the biological evaluation of the device modifications support the proposed AdVance XP Male Sling System is substantially equivalent to the predicate (K211847).

Performance Data

Performance testing was conducted on non-aged (T=0) samples and samples that were accelerated aged for 37 months (in order to support the 3 year device shelf life). 37 month real-time aging is ongoing. To demonstrate substantial equivalence of the AdVance XP Male Sling System to the predicate device (K211847), technological characteristics and performance criteria were evaluated using design verification bench testing. The FDA *Guidance for the Preparation of Premarket Notification Application for a Surgical Mesh* (issued on 02Mar1999) was utilized for preclinical mesh attribute evaluations. Mesh product characteristics such as mesh thickness, mesh weave characteristics, pore size, mesh density, tensile strength, and burst strength were evaluated through mesh material specification controls. Additional evaluations were performed through design testing on the final product assembly using internally developed product design specifications. The results of the performance testing demonstrate that the technological characteristics and performance criteria of the proposed AdVance XP Male Sling System are comparable to the predicate device (K211847) and functions as intended, equivalent to a device currently on the market for the same indications for use.

Conclusion

Based on the indication for use, technological characteristics, and performance data it can be concluded that the proposed AdVance XP Male Sling System is substantially equivalent to the predicate device AdVance XP Male Sling System (K211847) and is appropriate for the indications for use.