November 27, 2018

Boston Scientific Corporation
Kaitlyn Rainbow
Senior Regulatory Affairs Specialist
10700 Bren Road West
Minnetonka, MN 55343

Re: K182169
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: August 16, 2018
Received: August 17, 2018

Dear Kaitlyn Rainbow:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182169

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	Boston Scientific Corporation 10700 Bren Road West Minnetonka, MN 55343 USA Phone: 952-930-6000 Contact Person: Kaitlyn Rainbow Date Prepared: November 26, 2018
Device:	Device Name: AdVance™ XP Male Sling System Model: 720163-01 Common Name: Sub-Urethral Sling System; Surgical Mesh Classification Name: Surgical Mesh Classification Number: 21 CFR 878.3300 Regulatory Class: II Product Code: OTM Product Code Name: Mesh, Surgical, For Stress Urinary Incontinence, Male
Predicate Device	AdVance™ Male Sling System, K053371 No reference devices were used for this submission
Device Description	AdVance™ XP is a sling system which treats male stress urinary incontinence by repositioning the urethra with a suburethral mesh. The AdVance XP system is comprised of a permanently implanted monofilament polypropylene mesh sling, two needle passers used to implant the sling, SKW retractor and percutaneous needle. The sling is connected during the procedure to the needle passers through keyed connectors at each end of the sling which are removed after the sling is positioned. The sling repositions the bulbar urethra 2-4cms.
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.
Comparison of Technological Characteristics with the Predicate Device	AdVance™ XP and the predicate device achieve their mechanism of action by repositioning the bulbar urethra 2-4 cm. Both devices have the same mesh material, pore size, sling arm width, sheath and connectors, and transobturator surgical approach.

The technological differences that exist between the two devices are sling length, mesh weave, anchoring mechanism, and needle passer shape.

Performance Data

To demonstrate substantial equivalence of the AdVance™ XP to the predicate device, technological characteristics and performance criteria were evaluated using bench testing, biocompatibility testing, real world complaint data, clinical literature searches, and clinical evaluations.

The results from this testing and other data demonstrate that the technological characteristics and performance criteria of the AdVance™ XP are comparable to the predicate device and can perform in a manner equivalent to the devices currently on the market for the same intended use.

Conclusion

As the indications for use and fundamental scientific technology have not changed, non-clinical and clinical performance data supports a determination that the subject device is substantially equivalent to the predicate device, and that it is at least as safe and effective for its intended use.