June 29, 2023

Boston Scientific Corporation
Jotham Moon
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K231549
Trade/Device Name: Advantage™ Ultra System, Advantage Fit™ Ultra System, Lynx™ Ultra System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTN
Dated: May 26, 2023
Received: May 30, 2023

Dear Jotham Moon:

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,

Angel A. Soler-garcia -S

for
Jessica 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 *(if known)*

K231549

Device Name
Advantage™ Ultra System
Advantage Fit™ Ultra System
Lynx™ Ultra System

Indications for Use *(Describe)*

Advantage Ultra System and Advantage Fit Ultra System

The mesh implant is intended for use as a suburethral sling for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The Advantage Ultra System and the Advantage Fit Ultra System delivery devices are intended for use as an aid in insertion, placement, fixation, and anchoring of the Advantage Ultra surgical mesh during urogynecological procedures.

Lynx Ultra System

The mesh implant is intended for use as a suburethral sling for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The Lynx Ultra System delivery device is intended for use as an aid in insertion, placement, fixation, and anchoring of the Lynx Ultra surgical mesh during urogynecological procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for Advantage Ultra, Advantage Fit Ultra, and Lynx Ultra Systems

Date Prepared: June 29, 2023

A. Submitter

Boston Scientific Corporation
Urology Division
100 Boston Scientific Way
Marlborough, MA 01752

B. Contacts

Jotham Moon
Senior Regulatory Affairs Specialist
508-683-4208
Jotham.Moon@bsci.com

or

Brooke Cuddy
Principal Regulatory Affairs Specialist
508-683-6434
Brooke.Cuddy@bsci.com

C. Device Names

Trade name:	**Advantage™ Ultra System**
Model Number:	M0068502060
Common/Usual Name:	Mesh, surgical, synthetic, urogynecologic, for stress urinary incontinence, retropubic or transobturator
Regulation Number:	21 CFR §878.3300
Regulation Name:	Surgical Mesh
Classification:	Class II
Product Code:	OTN

Trade name:	**Advantage Fit™ Ultra System**
Model Number:	M0068502160
Common/Usual Name:	Mesh, surgical, synthetic, urogynecologic, for stress urinary incontinence, retropubic or transobturator
Regulation Number:	21 CFR §878.3300
Regulation Name:	Surgical Mesh
Classification:	Class II
Product Code:	OTN

Trade name:	**Lynx™ Ultra System**
Model Number:	M0068503060
Common/Usual Name:	Mesh, surgical, synthetic, urogynecologic, for stress urinary incontinence, retropubic or transobturator
Regulation Number:	21 CFR §878.3300
Regulation Name:	Surgical Mesh
Classification:	Class II
Product Code:	OTN

D. Predicate Devices

For purposes of establishing substantial equivalence, the proposed Ultra Products were compared to the predicate devices shown in the table below. The predicate devices have not been subject to a design-related recall.

Predicate Devices for Establishing Substantial Equivalence

	Predicate Devices
Device Trade Name:	Advantage Ultra System Advantage Fit Ultra System Lynx Ultra System
Regulation Name:	Surgical Mesh
Regulation Number:	21 CFR §878.3300
Classification:	Class II
Product Code:	OTN
510(k) Submitter/Holder:	Boston Scientific Corporation, Marlborough, MA
510(k) #/ Clearance Date	K211223 / Cleared July 21, 2021

E. Device Description

Advantage Ultra System and Advantage Fit Ultra System

The Advantage Ultra System and the Advantage Fit Ultra System are sterile, single-use systems each consisting of one delivery device and one blue mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh protected by two disposable polymer sleeves, two dilators, and one center tab. The sleeves and dilators are secured to the mesh by two polypropylene leader loops, and the center tab is secured to the mesh by a polyester lead. The two dilators at the distal ends of the mesh assembly are designed to be placed over the needle end of the delivery device.

The Advantage Ultra System and the Advantage Fit Ultra Systems are each packaged with their respective delivery device (Advantage Ultra or Advantage Fit Ultra delivery device). This is a single-use disposable delivery device that consists of a handle with a curved needle and a pusher component. The delivery device is designed to facilitate the passage of the mesh assembly through bodily tissues for retropubic placement.

The Advantage Fit Ultra System includes the same mid-urethral mesh implant as the Advantage Ultra System but differs in the design of the dilators and delivery devices. The needle portion of the Advantage Fit Ultra delivery device has a smaller outer diameter and a smaller bend radius and is offered to provide physicians with surgical options. The Advantage Fit Ultra dilators also have a smaller diameter to accommodate for the different needle size.

Lynx Ultra System

The Lynx Ultra System is a sterile, single-use system consisting of two delivery devices and one blue mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh protected by two disposable polymer sleeves, two dilators, and one center tab. The sleeves and dilators are secured to the mesh by two polypropylene leader loops, and the center tab is secured to the mesh by a polyester lead. At the distal ends of the mesh assembly there are association loops designed to be placed in the needle slot of the distal end of a delivery device.

The Lynx Ultra System is packaged with two Lynx System delivery devices. Each is a single-use disposable delivery device that consists of a handle with a curved needle with a needle slot for connection to the mesh assembly. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for suprapubic placement.

F. Intended Use/Indications for Use

Advantage Ultra System and Advantage Fit Ultra System

The mesh implant is intended for use as a suburethral sling for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The Advantage Ultra System and the Advantage Fit Ultra System delivery devices are intended for use as an aid in insertion, placement, fixation, and anchoring of the Advantage Ultra surgical mesh during urogynecological procedures.

Lynx Ultra System

The mesh implant is intended for use as a suburethral sling for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The Lynx Ultra System delivery device is intended for use as an aid in insertion, placement, fixation, and anchoring of the Lynx Ultra surgical mesh during urogynecological procedures.

G. Operating Principle

The mesh sling acts as a backboard to support the urethra during stress and straining events to prevent urine leakage.

H. Comparison of Key Technological/Performance Characteristics

The proposed Ultra Products are identical to the predicate devices cleared via K211223 in many aspects, as there are no changes to the intended use or indications for use, design, materials, sterilization, technological and performance characteristics, or principle of operation. The changes that are the subject of this premarket notification are limited to procedural steps within the Ultra Products' electronic Instructions for Use (eIFU)s. These changes modify the instructions and provide additional clarification related to release and removal of the disposable components of the mesh assembly. These changes impact the user interface by modifying the user workflow.

I. Substantial Equivalence

A direct comparison of key characteristics demonstrates that Ultra Products are substantially equivalent to the predicate devices in terms of intended use, principle of operation, technological and performance characteristics.

J. Performance Testing

Performance bench testing was conducted in the form of Design Validation and Summative Usability Evaluation to evaluate the eIFU modifications. The Design Validation provided objective evidence that all user needs impacted by the eIFU modifications were met and overall performance for the intended clinical use was acceptable. The Summative Usability Evaluation demonstrated that the Ultra Products continue to function as intended and do not raise new issues of safety or effectiveness compared to the predicate devices.

K. Conclusion

Based on the intended use/indications for use, comparison of key technological characteristics, and performance testing presented in this submission, it is concluded that the proposed Ultra Products are substantially equivalent to the established predicate devices.