August 6, 2021

Boston Scientific Corporation
% Brooke Cuddy
Principal Regulatory Affairs Specialist
Boston Scientific
100 Boston Scientific Way
Marlborough, MA 01752

Re: K211223
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

Dear Brooke Cuddy:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 21, 2021. Specifically, FDA is updating this SE Letter with an update to the contact zip code as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jessica K. Nguyen, Ph.D., OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, Jessica.Nguyen@fda.hhs.gov.

Sincerely,

Jessica K. Nguyen -S

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

July 21, 2021

Boston Scientific Corporation
% Brooke Cuddy
Principal Regulatory Affairs Specialist
Boston Scientific
100 Boston Scientific Way
Marlborough, MA 01564

Re: K211223
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: April 23, 2021
Received: April 26, 2021

Dear Brooke Cuddy:

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,

Andrew C. Durfor -S

For
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 *(if known)*
K211223

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

Indications for Use *(Describe)*
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.

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: April 22 2021

A. Submitter

Boston Scientific Corporation
Urology and Pelvic Health Division
100 Boston Scientific Way
Marlborough, MA 01752

B. Contacts

Rachel Nankervis
Regulatory Affairs Specialist II
508-683-4755
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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.

Predicate Devices for Establishing 'Substantial Equivalence'

	Primary Predicate (Predicate A)	**Secondary Predicate (Predicate B)**
Device Trade Name:	Advantage System Advantage Fit System Lynx System	Obtryx II System
Regulation Name:	Surgical Mesh	Surgical Mesh
Regulation Number:	21 CFR §878.3300	21 CFR §878.3300
Classification:	Class II	Class II
Product Code:	OTN	OTN
510(k) Submitter/Holder:	Boston Scientific Corporation, Marlborough, MA	Boston Scientific Corporation, Marlborough, MA
510(k) #/ Clearance Date	K020110 Cleared April 3, 2002	K121754 Cleared October 10, 2012

E. Device Descriptions

Advantage Ultra System

The Advantage Ultra System is a sterile, single-use system consisting of one delivery device and one 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 is packaged with the Advantage™ System Delivery Device previously cleared via K172565. 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.

Advantage Fit Ultra System

The Advantage Fit Ultra System is a sterile, single-use system consisting of one delivery device and one 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 Fit Ultra System is packaged with the Advantage Fit™ System Delivery Device previously cleared via K172565. 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.

Lynx Ultra System
The Lynx Ultra System is a sterile, single-use system consisting of two delivery devices and one 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 previously cleared via K172565. 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

The proposed Ultra products Intended Use/Indications for use statement is as follows:

> *"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 Intended Use statement is identical to that of Predicate A and Predicate B, except for the addition of the word "female". The female patient population was implied but not explicitly stated in the predicate device labeling. The explicitly stated patient population in the Intended Use/Indications for Use statement for the proposed Ultra products are equivalent to both Predicate A and Predicate B and does not affect the safety and effectiveness of the devices.

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 Ultra products are identical, equivalent or similar to both Predicate A (K020110) and Predicate B (K121754) devices in terms of technological characteristics and fundamental design.

As compared to Predicate A, the Ultra products' mesh implant component and placement route are identical. The proposed Ultra products and Predicate A have technological differences that are limited solely to the mesh assembly components (disposable, non-implantable) and the corresponding operational instructions related to these modified components. The proposed Ultra products' disposable mesh assemblies leverage the fundamental technologies used in Predicate B. The primary differences between the Ultra products and Predicate B are the mesh implant length and the placement route.

The following is a summary of the technological characteristics of the proposed Ultra devices compared to the legally marketed predicate devices, including a list of the technological differences:

- Equivalent Intended Use (Predicates A and B)

- Identical environment of use (healthcare facility/hospital) (Predicates A and B)
- Identical permanent mesh implant component (Predicate A)
- Identical sterilization method (ethylene oxide) (Predicates A and B)
- Identical placement routes of implant (Predicate A)
- Identical procedural steps
    - Insertion and placement of the mesh implant (Predicate A)
    - Removal of the mesh assembly after mesh implant is placed (Predicate B)
- Identical delivery devices (Predicate A and B - delivery devices cleared via K172565)
- Similar design and fundamental technology of the mesh assemblies (Predicate B), with the following minor modifications that do not raise new questions of safety and effectiveness
    - Sleeves– material formulation and increased length
    - Center tab– colorant
    - Center tab lead– secondary resin supplier
    - Leader loops– increased length

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, technological and performance characteristics.

J. Biocompatibility

The Ultra products' mesh implants, mesh assemblies, and delivery devices are all patient-contacting components. The mesh slings are categorized as implants components that contact tissue/bone for a permanent duration (> 30 days). The mesh assemblies and delivery devices are categorized as externally communicating components that contact tissue/bone for limited duration (≤ 24 hours). Biocompatibility testing demonstrates that all patient contacting materials meet applicable biocompatibility standards per **ISO 10993-1:2018** and the FDA Guidance *Use of International Standard **ISO 10993-1*** "*Biological evaluation of medical devices. Evaluation and testing within a risk management process*."

K. Performance Testing

Performance testing was conducted on non-aged samples and samples that were accelerated aged for the equivalent of 13 months, in order to support a 1-year shelf life. The performance tests completed to demonstrate that the Ultra products function as intended include:

- Dimensional tests
- Tensile strength tests
- Full functional tests
    - User evaluations
    - Packaging tests
    - Biocompatibility
    - Sterility

The results of performance testing demonstrate that the proposed products function as intended and meet specification requirements, which were established considering anticipated conditions of use, for the stated shelf life.

L. 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 predicates.