December 20, 2017

Anand Patel
Regulatory Affairs Specialist II
100 Boston Scientific Way
Marlborough, MA 01752

Re: K172565
Trade/Device Name: Advantage™ System Delivery Device, Advantage Fit™ System Delivery Device, Lynx™ System Delivery Device, Solyx™ SIS Delivery Device, Obtryx™ (Curved) Delivery Device, Obtryx™ (Halo) Delivery Device, Obtryx™ II (Curved) Delivery Device, Obtryx™ II (Halo) Delivery Device
Regulation Number: 21 CFR§ 884.4910
Regulation Name: Specialized Surgical Instrumentation for use with Urogynecologic Surgical Mesh
Regulatory Class: II
Product Code: PWJ
Dated: November 17, 2017
Received: November 20, 2017

Dear Anand Patel:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Charles Viviano -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)*
K172565

Device Name
Advantage™ System Delivery Device, Advantage Fit™ System Delivery Device, Lynx™ System Delivery Device, Solyx™ SIS Delivery Device, Obtryx™ (Curved) Delivery Device, Obtryx™ (Halo) Delivery Device, Obtryx™ II (Curved) Delivery Device, Obtryx™ II (Halo) Delivery Device

Indications for Use *(Describe)*
The Advantage System Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Advantage surgical mesh during urogynaecological procedures.

The Advantage Fit System Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Advantage Fit surgical mesh during urogynaecological procedures.

The Lynx System Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Lynx surgical mesh during urogynaecological procedures.

The Solyx SIS Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Solyx SIS surgical mesh during urogynaecological procedures.

The Obtryx (Curved) Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Obtryx surgical mesh during urogynaecological procedures.

The Obtryx (Halo) Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Obtryx surgical mesh during urogynaecological procedures.

The Obtryx II (Curved) Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Obtryx II surgical mesh during urogynaecological procedures.

The Obtryx II (Halo) Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Obtryx II surgical mesh during urogynaecological 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.

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510(k) Summary
K172565

A. Date Prepared

December 20, 2017

B. Sponsor

Boston Scientific Corporation
Urology and Women's Health Division
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C. Contact

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D. Device Name(s)

Trade name: **Advantage™ System Delivery Device**
Common/usual name: Delivery Devices
Regulation Number: 21 CFR 884.4910
Regulation Name: Specialized Surgical Instrumentation for Use with Urogynecologic Surgical Mesh
Classification: Class II
Product Code: PWJ (instrumentation, surgical mesh, urogynecologic, stress urinary incontinence)

Trade name: **Advantage™ Fit System Delivery Device**
Common/usual name: Delivery Devices
Regulation Number: 21 CFR 884.4910
Regulation Name: Specialized Surgical Instrumentation for Use with Urogynecologic Surgical Mesh
Classification: Class II
Product Code: PWJ (instrumentation, surgical mesh, urogynecologic, stress urinary incontinence)

Trade name: **Lynx™ System Delivery Device**
Common/usual name: Delivery Devices
Regulation Number: 21 CFR 884.4910
Regulation Name: Specialized Surgical Instrumentation for Use with Urogynecologic Surgical Mesh
Classification: Class II
Product Code: PWJ (instrumentation, surgical mesh, urogynecologic, stress urinary incontinence)

Trade name: **Solyx™ SIS Delivery Device**
Common/usual name: Delivery Devices
Regulation Number: 21 CFR 884.4910
Regulation Name: Specialized Surgical Instrumentation for Use with Urogynecologic Surgical Mesh
Classification: Class II
Product Code: PWJ (instrumentation, surgical mesh, urogynecologic, stress urinary incontinence)

Trade name: **Obtryx™ (Curved) Delivery Device)**
Common/usual name: Delivery Devices
Regulation Number: 21 CFR 884.4910
Regulation Name: Specialized Surgical Instrumentation for Use with Urogynecologic Surgical Mesh
Classification: Class II
Product Code: PWJ (instrumentation, surgical mesh, urogynecologic, stress urinary incontinence)

Trade name: **Obtryx™ (Halo) Delivery Device**
Common/usual name: Delivery Devices
Regulation Number: 21 CFR 884.4910
Regulation Name: Specialized Surgical Instrumentation for Use with Urogynecologic Surgical Mesh
Classification: Class II
Product Code: PWJ (instrumentation, surgical mesh, urogynecologic, stress urinary incontinence)

Trade name: **Obtryx™ II (Curved) Delivery Device**
Common/usual name: Delivery Devices
Regulation Number: 21 CFR 884.4910
Regulation Name: Specialized Surgical Instrumentation for Use with Urogynecologic Surgical Mesh
Classification: Class II
Product Code: PWJ (instrumentation, surgical mesh, urogynecologic, stress urinary incontinence)

Trade name: **Obtryx™ II (Halo) Delivery Device**
Common/usual name: Delivery Devices
Regulation Number: 21 CFR 884.4910
Regulation Name: Specialized Surgical Instrumentation for Use with Urogynecologic Surgical Mesh
Classification: Class II
Product Code: PWJ (instrumentation, surgical mesh, urogynecologic, stress urinary incontinence)

E. Predicate Device(s)

Trade name: Advantage™ System, Advantage Fit™ System, Lynx™ System
Common/usual name: Surgical Mesh
Regulation Number: 21 CFR 878.3300
Classification: Class II
Product Code: OTN
Premarket Notification: Boston Scientific, K020110

Trade name: Solyx™ SIS System
Common/usual name: Surgical Mesh
Regulation Number: 21 CFR 878.3300
Classification: Class II
Product Code: PAH
Premarket Notification: Boston Scientific, K081275

Trade name: Obtryx™ II System (Curved & Halo)
Common/usual name: Surgical Mesh
Regulation Number: 21 CFR 878.3300
Classification: Class II
Product Code: OTN
Premarket Notification: Boston Scientific, K121754

The predicate devices have not been subject to a design-related recall.

F. Device Description

The subject devices are not sold individually and are only offered packaged as part of a surgical mesh system. Device descriptions specific to each delivery device are italicized below within each existing system description.

Advantage™ System and Advantage Fit™ System
The Advantage System and the Advantage Fit System are sterile, single use systems, consisting of one delivery device and one mesh assembly. Each mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the mesh assembly are two dilators designed to be placed over the needle end of the delivery device. *The disposable delivery device 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 transvaginal placement.

Lynx™ System
The Lynx System is a sterile, single use system consisting of two (2) delivery devices and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. 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 the delivery device. *The disposable delivery device consists of a handle with a curved needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for suprapubic placement.*

Solyx™ SIS System
The Solyx SIS (Single Incision Sling) System is a sterile single use system consisting of one (1) delivery device and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh with polypropylene carriers at each end of the distal mesh. The carrier is designed to be placed on the tip of the delivery device. *The disposable delivery device consists of a handle, a stainless steel shaft and a deployment mechanism. The delivery device is designed to facilitate the passage of the mesh assembly through bodily tissues for placement into the obturator internus muscle.*

Obtryx™ System (Curved & Halo)
The Obtryx Sling Systems (Curved or Halo) are sterile, single use system consisting of two (2) delivery devices and one (1) mesh assembly. Each mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. 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 the delivery devices. *The disposable delivery devices consist of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.*

Obtryx™ II System (Curved & Halo)
The Obtryx II Systems (Curved or Halo) are sterile, single use system consisting of two (2) delivery devices and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh with dilator legs and a center tab. At the distal ends of the dilator legs there are association loops designed to be placed in the needle slot of the distal end of the delivery devices. *The disposable delivery devices consist of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.*

G. Comparison of Indications for Use with Predicate Devices

Advantage™ Delivery Device		
Indication for Use	**K172565 (Subject Device)**	**K020110 (Predicate Device)**
	The Advantage System Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Advantage surgical mesh during urogynaecological procedures.	The mesh implant is intended as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Advantage™ Fit Delivery Device		
Indication for Use	**K172565 (Subject Device)**	**K020110 (Predicate Device)**
	The Advantage Fit System Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Advantage Fit surgical mesh during urogynaecological procedures.	The mesh implant is intended as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Lynx™ Delivery Device		
Indication for Use	**K172565 (Subject Device)**	**K020110 (Predicate Device)**
	The Lynx System Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Lynx surgical mesh during urogynaecological procedures.	The mesh implant is intended as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Solyx™ SIS Delivery Device		
Indication for Use	**K172565 (Subject Device)**	**K081275 (Predicate Device)**
	The Solyx SIS Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Solyx SIS surgical mesh during urogynaecological procedures.	The mesh implant is intended as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Obtryx™ & Obtryx™ II Delivery Device		
Indication for Use	**K172565 (Subject Device)**	**K121754 (Predicate Device)**
	The Obtryx (Curved) Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Obtryx surgical mesh during urogynaecological procedures. The Obtryx (Halo) Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Obtryx surgical mesh during urogynaecological procedures. The Obtryx II (Curved) Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Obtryx II surgical mesh during urogynaecological procedures. The Obtryx II (Halo) Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Obtryx II surgical mesh during urogynaecological procedures.	The mesh implant is intended as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The indications for use statements for subject devices and the predicate devices are not identical, as the predicate devices are surgical mesh systems for treatment of stress urinary incontinence. The intended use of the subject and predicate devices is the same, as the subject devices are an accessory to a surgical mesh.

H. Comparison of Technological Characteristics

Device(s)	Subject Device	Predicate Device
	K172565	**K020110** **K081275** **K121754**
General Device Characteristics		
Patient contact	< 24 hours (tissue/bone)	Permanent (tissue/bone)
Operating Principle	Aid in insertion, placement, fixation, or anchoring of surgical mesh	Sub/Mid-Uretheral mesh sling systems for treatment of stress urinary incontinence
Device Design	Surgical mesh instrumentation	Surgical mesh
Materials	Plastic Stainless steel	Polypropylene
Shelf-life	3 years	3 years
Sterility	EO	EO

As discussed above, the subject devices have different technological characteristics from the predicate devices. The predicate devices are surgical mesh whereas the subject devices are used for the placement of surgical mesh. Briefly, the predicate devices differ from the subject devices as follows:

1. Operating principle
2. Device Design
3. Materials

The differences between the subject devices and the predicate devices can raise different types of safety and effectiveness questions, as we are comparing an accessory and parent device. The differences in technological characteristics were evaluated through completion of special controls (performance testing, biocompatibility, shelf-life/reprocessing, labeling, and sterilization) published in the final order reclassifying urogynecologic surgical mesh instrumentation from class I to class II published on January 6, 2017.

I. Non-Clinical Performance Test Summary

The following tests were performed to demonstrate that the proposed subject devices met the applicable design and performance requirements and support a determination of substantial equivalence under the specified testing parameters. These tests include:

- Sterilization Validation
- Package integrity testing following real-time aging
    - Dye Penetration
    - Seal Strength
    - Visual Inspection
- Dimensional Tests
- Functional Tests
- Distribution Challenge of Packaging

- Biocompatibility
    - Cytotoxicity
    - Sensitization
    - Irritation or Intracutaneous Reactivity
    - Acute systemic toxicity
- Shelf-life Testing

The results of performance testing demonstrate the subject devices are biocompatible, have sufficient mechanical performance for its intended use, and support a three-year shelf life.

J. Conclusion

The Delivery Devices for Surgical Mesh Systems are substantially equivalent and complies with the special controls outlined in 21 CFR 884.4910, Specialized surgical instrumentation for use with urogynecologic surgical mesh.