



November 3, 2017

Boston Scientific Corporation
Michelle Becker
Regulatory Affairs Specialist
Urology and Pelvic Health
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K172060
Trade/Device Name: Capio™ SLIM Suture Capturing Device
Regulation Number: 21 CFR 884.4910
Regulation Name: Specialized surgical instrumentation for use with urogynecologic
surgical mesh
Regulatory Class: Class II
Product Code: PWI
Dated: September 29, 2017
Received: October 2, 2017

Dear Michelle Becker:

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,

Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known)

K172060

Device Name

Capio™ SLIM Suture Capturing Device

Indications for Use (Describe)

The Capio™ SLIM Suture Capturing Device is intended for use in general suturing applications during surgery to assist in the placement of suture material in tissues at the operative site. The Capio™ SLIM Suture Capturing Device is to be used with sensory and/or direct visual control.

The Capio SLIM Suture Capturing Device is also intended for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic 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 for Capiro™ SLIM Suture Capturing Device (K172060)

A. Date Prepared

November 2, 2017

B. Sponsor

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

C. Contact

Rachel Nankervis
Specialist I, Regulatory Affairs
Phone: 508-683-4755
Fax: 508-683-5041
Rachel.Nankervis@bsci.com

Or

Michelle Becker
Principal Specialist, Regulatory Affairs
Phone: 508-210-6988
Fax: 508-683-5041
Michelle.Becker@bsci.com

D. Device Name

Trade Name: Capiro™ SLIM Suture Capturing Device
Common/usual Name: Suture Placement Device
Regulation Number: 21 CFR 884.4910
Regulation Name: Specialized surgical instrumentation for use with urogynecologic surgical mesh
Classification: Class II
Product Code: PWI

E. Predicate Device(s)

Trade Name: Pinnacle Lite Pelvic Floor Repair Kit,
 Posterior Uphold Lite Vaginal Support System
 Common/usual Name: Surgical Mesh for transvaginal
 pelvic organ prolapse repair
 Regulation Number: 21 CFR 878.3300
 Regulation Name: Surgical mesh
 Classification: II
 Product Code: OTP
 Premarket Notification: K122459

F. Device Description

The Capiro™ SLIM Suture Capturing Device is urogynecologic mesh instrumentation used with urogynecologic surgical mesh. The subject device is also intended for use in general suturing applications during surgery to assist in placement of suture material in tissues, and assist in insertion or anchoring of surgical mesh for transabdominal pelvic organ prolapse repair.

The Capiro™ SLIM Suture Capturing Device is a sterile, single use device and is designed to be used by the physician to facilitate the placement of sutures in difficult to access locations during open surgical procedures. The Capiro™ SLIM device is also designed to throw, catch and retrieve sutures in one step. The device consists of a one-hand-activated plunger at the proximal end, a tubular shaft and a curved needle driver at the distal end. Depressing the plunger actuates the carrier and drives the suture/dart through the tissue. The needle is automatically caught by the device's needle catch mechanism for easy suture tying, or the device may be re-loaded for additional suture throws.

G. Comparison of Intended Use with Predicate Device

	K172060 (Subject Device)	K122459 (Predicate Device)
Indications for Use	<p>The Capiro™ SLIM Suture Capturing Device is intended for use in general suturing applications during surgery to assist in the placement of suture material in tissues at the operative site. The Capiro™ SLIM Suture Capturing Device is to be used with sensory and/or direct visual control.</p> <p>The Capiro SLIM Suture Capturing Device is also intended for use as an</p>	<p>The Pinnacle Lite Pelvic Floor Repair Kit is indicated for tissue reinforcement in women with pelvic organ prolapse, for transvaginal repair of posterior vaginal vault prolapse.</p> <p>The Uphold Lite Vaginal Support System is indicated for tissue reinforcement in women with pelvic organ prolapse, for transvaginal repair of anterior and apical vaginal vault prolapse</p>

	aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures.	
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The indications for use statements for subject device and the predicate device are not identical, as the predicate device is a surgical mesh that is indicated pelvic to treat organ prolapse. The intended use of the subject and predicate device is the same, as the subject device is an accessory to a surgical mesh.

H. Comparison of Technological Characteristics

Device(s):	K172060 (Subject Device)	K122459 (Predicate Device)
General Device Characteristics		
Patient contact	< 24 hours (tissue/bone)	Permanent (tissue/bone)
Operating Principle	Aid in placement of surgical mesh/suture	Transvaginal repair of anterior and apical vaginal wall prolapse
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 device has different technological characteristics from the predicate device. The predicate device is a surgical mesh whereas the subject device is used for the placement of surgical mesh. Briefly, the predicate device differs from the subject device as follows:

1. Operating principle
2. Device Design
3. Materials

The differences between the subject device and the predicate device 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 Capio Slim Device 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 Test
- Functional Test
- Compression Test
- Tip Tensile Test
- Side Load Deflection
- Top Load Deflection
- Needle Retention Test
- Catch Pull Test
- Actuation Test
- Distribution Challenge of Packaging
- Biocompatibility
 - Cytotoxicity
 - Sensitization
 - Irritation or Intracutaneous Reactivity
 - Acute systemic toxicity
 - Material-Mediated Pyrogenicity
- Shelf-life Testing

The results of performance testing demonstrate the Capio SLIM Suture Capturing Device is biocompatible, has sufficient mechanical performance for its intended use, and supports a three-year shelf life.

J. Conclusion

The Capio SLIM is substantially equivalent and complies with the special controls outlined in 21 CFR 884.4910, Specialized surgical instrumentation for use with urogynecologic surgical mesh.