510(k) Summary for Pinnacle LITE Pelvic Floor Repair Kit, Posterior and Uphold LITE Vaginal Support System

Date Prepared: Sep 30, 2013

A. Sponsor

Boston Scientific Corporation
Urology and Gynecology Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

Michelle Berry
Senior, Regulatory Affairs Specialist
508-683-4941
or
Donna Gardner
Director, Regulatory Affairs
508-683-4398

C. Device Name

Trade name:	Pinnacle LITE Pelvic Floor Repair Kit, Posterior and Uphold LITE Vaginal Support System
Common/usual name:	Surgical Mesh
Classification Name:	OTP – Mesh, Surgical, Synthetic, Urogynecologic, for Pelvic Organ Prolapse, Transvaginally Placed 21 CFR 878.3300, Class II

D. Predicate Device(s)

Trade name:	Pinnacle LITE Pelvic Floor Repair Kit, Posterior and Uphold LITE Vaginal Support System
Common/usual name:	Surgical Mesh
Classification Name:	OTP – Mesh, Surgical, Synthetic, Urogynecologic, for Pelvic Organ Prolapse, Transvaginally Placed 21 CFR 878.3300, Class II
Premarket Notification:	Boston Scientific, K103426

E. Device Description

The proposed devices were submitted for a leg assembly modification to the previously cleared LITE Pelvic Floor Repair Kits: Pinnacle LITE Posterior and Uphold LITE Vaginal Support System. The modification to the leg assembly removes the mesh tack welds, separator weld and adds a second leader loop to maintain the mesh leg location within the sleeve to facilitate mesh leg placement. There are no changes to the mesh design, shape, size, material or indications for use.

The proposed mesh configurations were designed for performing transvaginal vaginal wall repair to facilitate treatment of anterior apical and posterior prolapse repairs. These devices are sterile, single use devices, consisting of one light-weight synthetic mesh assembly and a needle holder.

The mesh assembly consists of a macroporous polypropylene knitted mesh body with integrated legs that are protected by disposable polymer sleeves. At the distal end of the disposable polymer sleeve is a lead with dart designed for use with the Capio™ Suture Capturing Device. The disposable lead was designed to facilitate the passage of the proposed mesh through bodily tissues for placement.

F. Intended Use

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.

The Uphold LITE Vaginal Support System is indicated for tissue reinforcement in women with pelvic organ prolapse, for the transvaginal repair of anterior and apical vaginal wall prolapse.

G. Technological Characteristics

The proposed device has the same identical mesh fiber materials and fiber diameter as the predicate. The leg assembly will include a second leader loop to maintain the mesh leg location within the sleeve to facilitate mesh leg placement.

H. Substantial Equivalence

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" and "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh", a direct comparison of key characteristics demonstrates that the proposed mesh is substantially equivalent to the predicate mesh in terms of intended use, technological characteristics, and performance characteristics. The proposed device is as safe, as effective, and performs as well as the predicate devices.

I. Performance Testing (Bench Evaluation)

Boston Scientific conducted performance testing in support of the leg assembly change and the following testing was completed:

- Leg Assembly Flexibility
- Mesh/Leg Tensile
- Leader/Dilator/Sleeve Tensile
- Sleeve Removal

The results of the performance testing demonstrate equivalence of the proposed and predicate devices. The LITE Pelvic Floor Repair Kits are considered safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 18, 2013

Boston Scientific Corporation
Urology and Women's Health
Michelle M. Berry
Principal Specialist, Regulatory Affairs
100 Boston Scientific Way
Marlborough, MA 01752

Re: K122459
Trade/Device Name: Pinnacle LITE Pelvic Floor Repair Kit, Posterior and Uphold LITE Vaginal Support System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTP
Dated: (Date on orig SE ltr): November 2, 2012
Received: (Date on orig SE ltr): November 5, 2012

Dear Michelle M. Berry,

This letter corrects our substantially equivalent letter of December 13, 2012.

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 28 May 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.

If you desire specific advice for your device on our labeling regulation (21 CFR 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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 Statement

510(k) Number (if Known): K122459

Device Name: Pinnacle LITE Pelvic Floor Repair Kit, Posterior and Uphold LITE Vaginal Support System

Indications For Use:

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.

The Uphold LITE Vaginal Support System is indicated for tissue reinforcement in women with pelvic organ prolapse, for the transvaginal repair of anterior and apical vaginal wall prolapse.

Prescription Use X (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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