SECTION 5 **510K SUMMARY**

510(k) Summary for Upsylon Y mesh

DEC 18 2012

A. Sponsor

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

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or

Donna Gardner
Director, Regulatory Affairs
508-683-4398
gardnerd@bsci.com

C. Device Name

Trade name: Upsylon Y mesh
Common/usual name: Surgical Mesh
Classification Name: OTO– Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal and Uterine Prolapse, Transabdominally Placed
21 CFR 878.3300, Class II

D. Predicate Device

Trade name: LITE Pelvic Floor Repair Kits
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

Trade name: Restorelle Y
Common/usual name: Surgical mesh
Classification Name: OTO– Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal and Uterine Prolapse, Transabdominally Placed
21 CFR 878.3300, Class II

Premarket Notification: Coloplast, K112322

SECTION 5 **510K SUMMARY**

E. Device Description

Upsylon Mesh is a preformed Y shaped lightweight polypropylene mesh consisting of two vaginal mesh arms and one sacral mesh arm. The Upsylon mesh is blue in color with a non-colored centering line.

F. Intended Use

Intended for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy, laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

G. Technological Characteristics

The Upsylon Y mesh is a preconfigured, lightweight polypropylene mesh and has the same technological characteristics and fundamental Y mesh design as the predicate Restorelle Y.

H. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the proposed Y mesh is substantially equivalent to the predicate device in terms of intended use, technological characteristics, and performance characteristics. The Upsylon Y mesh is as safe, as effective, and performs as well as the predicate devices.

I. Performance Testing (Bench and User Evaluation)

Boston Scientific has conducted a user evaluation in cadavers which evaluated placement of the mesh. Performance testing was completed with samples aged at T=0 and T=7 months accelerated aging in support of the Upsylon Y mesh configuration. The following testing was completed:

- Y mesh leg tensile
- Y mesh leg elongation
- Y mesh attachment strength

Performance data for biocompatibility and mesh characterization provided in K103426 for the LITE Pelvic Floor Repair Kits supports the Upsylon Y mesh. The results of the performance testing demonstrate equivalence of the Upsylon Y mesh to the predicate meshes.

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

December 18, 2012

Boston Scientific Corporation
Urology/Women's Health
% Ms. Lauren B. Anderson, RAC
Senior Specialist, Regulatory Affairs
100 Boston Scientific Way
MARLBOROUGH MA 01752

Re: K122794
Trade/Device Name: Upsylon Y mesh
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: November 28, 2012
Received: November 29, 2012

Dear Ms. Anderson:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

SECTION 4 **INDICATIONS FOR USE**

Indications for Use Statement

510(k) Number ~~To be determined:~~ K122794

Device Name Upsylon Y mesh

Indications For Use

The Upsylon Y mesh is intended for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy, laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

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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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122794