Boston Scientific Corporation CONFIDENTIAL

510(k) Summary for Surgical Mesh

A. Sponsor

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

B. Contact

Janet A. McGrath
Principal Specialist Global Regulatory Affairs
508-683-4726
or
Donna Gardner
Director, Regulatory Affairs
508-683-4398

C. Device Name

Tradename: Advantage™ System , Advantage Fit™ and Lynx ™ System
Common/usual name: Surgical Mesh
Classification Name: OTN – Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II

D. Predicate Device(s)

Tradename:
1. Tension Free Vaginal Tape
2. Trelex Mesh
3. BioSling Bioabsorable Polymer Sling and Surgical Mesh
4. Suspend Sling

Common/usual name: Surgical Mesh
Classification Name: OTN- Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II
Premarket Notification:
1. K974098 (TVT)
2. K945377 (BSC)
3. K010533 (INJECTX, INC)
4. K980483 (MENTOR)

E. Device Description

The proposed sling is a sterile, single use device, consisting of a synthetic mesh sling assembly and packaged with a delivery device. The mesh assembly consists of a knitted polypropylene monofilament fiber mesh body implant, dilators, mesh sleeve and center tab.

Addition of documentation for Traditional 510(k) K020110
Surgical Mesh
April 11, 2013

Accessories

The proposed sling is packaged with other legally marketed accessories (e.g., Delivery Device; Class I exempt: 876.4730 Manual gastroenterology-urology surgical instrument and accessories).

F. Intended Use

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

G. Technological Characteristics

The intended use of the surgical mesh is equivalent to all the predicate devices listed. As stated in this 510K the materials and the technological characteristics are equivalent to the predicate Tension Free Vaginal Tape, K974098.

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 sling is substantially equivalent to the predicate sling in terms of intended use, technological characteristics, and performance characteristics tested. The proposed sling is as safe, as effective, and performs as well as the predicate device.

I. Non-Clinicial Testing

Material testing was performed to demostrate that the material properites are suitable for the intended use.

Bench testing was performed to demostrate that the device as manufactured meets performance specifications. Test results demostrate that the device meets the predetermine specifications and is acceptable for clinical use.

Biocompatiblity testing was performed in accordance to standard EN ISO 10993-1 for each of the patient contacting materials, and results demonstrate that the device is biocompatible for its intended use.

Conclusion:

Based on material, biocompatiblity, bench testing, and the proposed device labeling, the device is substantially equivalent to the identified predicate devices previously classified under 21 CFR 878.3300 as Class II, mesh surgical, polymeric, in terms of intended use and thefore do not adversely effect safety and effectiveness.

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

September 13, 2013

Boston Scientific Corporation
Urology and Gynecology Division
% Lorraine M. Hanley
Director
One Boston Scientific Place
Natick, MA 01760

Re: K020110
Trade/Device Name: Advantage™ System, Advantage™ Fit System and Lynx™ System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated (Date on orig SE ltr): January 9, 2002
Received (Date on orig SE ltr): January 11, 2002

Dear Lorraine M. Hanley,

This letter corrects our substantially equivalent letter of April 3, 2002.

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 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,

Herbert P. Lerner -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

Indications for Use Statement

510(k) Number (if Known): K020110

Device Name: Advantage™ System, Advantage™ Fit System and Lynx™ System

Indications For Use:

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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

Herbert P. Lerner -S