

510(k) Summary for Surgical Mesh

A. Sponsor

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

AUG 27 2008

B. Contact

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

C. Device Name

Tradename: Surgical Mesh, (SIS)
Common/usual name: Surgical Mesh
Classification Name: FTL – Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II

D. Predicate Device(s)

Tradename: Advantage® Transvaginal Mid Urethral Sling System
Advantage Fit™ System
Lynx ® Suprapubic Mid Urethral Sling System
Obtryx® Transobturator Mid Urethral Sling System
Prefyx PPS® System
AMS MiniArc™ Sling System

Common/usual name: Surgical Mesh
Classification Name: FTL- Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II

Premarket

Notification: Boston Scientific Corporation: K020110, K040787
American Medical System, Inc.: K073703

E. Device Description

The proposed device 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 with polypropylene carriers, each are attached to separate ends.

Accessories

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

K081275
K9 2002

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 proposed device has the same and/or equivalent technological characteristics (i.e. mesh design and mesh material) as the predicate(s).

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 tested. The proposed device is as safe, as effective, and performs as well as the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Boston Scientific Corporation
% Ms. Janet A. McGrath
Principal Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

AUG 27 2008

Re: K081275

Trade/Device Name: Surgical Mesh, (SIS)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: August 13, 2008
Received: August 14, 2008

Dear Ms. McGrath:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

Page 2 – Ms. Janet A. McGrath

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081275

Indications for Use Statement

510(k) Number (if Known): K081275

Device Name: Surgical Mesh , (SIS)

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.

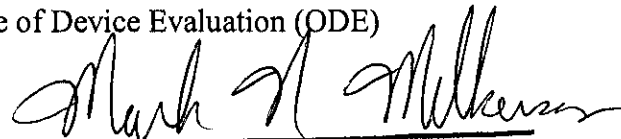
Prescription Use X
(21 CFR 801 Subpart D)

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)



(Division Sign-Off)
Division of General Restorative,
and Neurological Devices

510(k) Number K081275