

K071957

510(k) Summary for the Pinnacle™ Pelvic Floor Repair Mesh

A. Sponsor

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

B. Contact

NOV 08 2007

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

C. Device Name

Tradename: Pinnacle™ Pelvic Floor Repair Kits
Common/usual name: Surgical Mesh
Classification Name: FTL – Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II

D. Predicate Device(s)

Tradename: Polyform Synthetic Mesh
Common/usual name: Surgical Mesh
Classification Name: FTL- Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II
Premarket Notification: Proxy Biomedical, Ltd., K051245

E. Device Description

The proposed device is a sterile, single use device, consisting of a synthetic mesh assembly and needle holder. The mesh assembly consists of a 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 needle designed for use with the currently legally marketed Capiro™ Open Access Suture Capturing Device. The disposable lead was designed to facilitate the passage of the proposed mesh through bodily tissues for placement. The proposed mesh will be offered in three mesh models: Total, Anterior/Apical and Posterior designed for performing total vaginal repair, anterior vaginal defects and posterior and/or apical vaginal vault defects respectively.



JAN 13 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Boston Scientific Corporation
% Ms. Michelle M. Berry
Senior, Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K071957
Trade/Device Name: Undetermined
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: October 3, 2007
Received: October 4, 2007

Dear Ms. Berry:

This letter corrects our substantially equivalent letter of November 8, 2007.

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 (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 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.

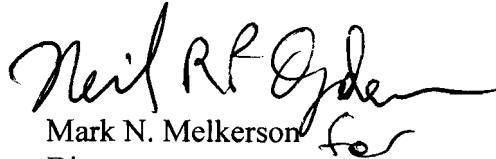
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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This letter will allow you to continue 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink that reads "Neil R. Melkerson". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

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

Enclosure

Indications for Use Statement

510(k) Number (if Known): K071957

Device Name: Undetermined

Indications For Use:

The Pinnacle™ Pelvic Floor Repair Kits are indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor for vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

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-)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K071957