

K091180

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17. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

SUBMITTER Ms Melissa Peloquin
Director of Office Administration
Mpathy Medical Devices Inc.
175 Paramount Drive
Raynham, MA 02767

JUL 14 2009

CONTACT PERSON Dr Caroline Stretton
Quality & Regulatory Affairs Director
Mpathy Medical Devices, Ltd.
208 Wright Business Centre
Lonmay Road
Glasgow G33 4EL (United Kingdom)

DATE PREPARED 15 April 2009

CLASSIFICATION Surgical Mesh; ref. 21 CFR 878.3300
Product Code **PAH**
Class II

COMMON NAME Surgical mesh

PROPRIETARY NAME Minitape® Urethral Sling

PREDICATE DEVICE K073646 – Modified Minitape Urethral Sling (Mpathy Medical Devices)
K020007 - SAFYRE Sling (Corniche, LLC)
K033310 - Remeex System (Remeex)
K011251, K013355, K021263 & K020663 - SPARC Sling System (American Medical Systems)
K052401 - TVT® Secur (Gynecare)
K073703 - MiniArc® (American Medical Systems).

DEVICE DESCRIPTION The subject device is a surgical mesh. The proprietary mesh is supplied along with ancillary tools for placement of the device (convenience kit). The kit consists of: Minitape Urethral Sling (mesh) intended to be used as a pubourethral sling for the treatment of female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency; Disposable needle introducers, optionally used to aid in placement of the Minitape mesh; Polydioxanone absorbable sutures (CP Medical; Portland, OR), used to secure the mesh in place; Polypropylene suture bolsters (Ethicon Inc.; Sommerville, NJ), optionally used to aid in tightening ("snugging") the mesh following surgical placement.

INDICATIONS

Minitape® Urethral Sling is indicated for the surgical treatment of urodynamically proven female urinary stress incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

TECHNOLOGICAL CHARACTERISTICS

Minitape® Urethral Sling has the same intended use, general design, material and fundamental scientific technology as the predicate Modified Minitape Urethral Sling device, with the exception of a shorter overall sling length.

TESTING

The device has been subjected to in-vitro and in-vivo testing which demonstrate the ability of the device to adequately restrain urethral tissue under conditions in excess of those encountered during normal clinical use.



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

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SEP 28 2012

Re: K091180
Trade/Device Name: Minitape Urethral Sling
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAH
Dated: July 1, 2009
Received: July 8, 2009

Dear Dr. Stretton:

This letter corrects our substantially equivalent letter of July 14, 2009.

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.

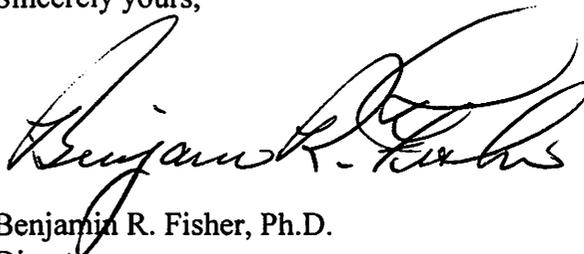
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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" (21 CFR 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,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, with a large initial "B" and "F".

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

16. STATEMENT FOR INDICATIONS FOR USE

510(k) Number: _____

Device Name: Minitape Urethral Sling

Indications for Use: Minitape Urethral Sling is indicated for the surgical treatment of urodynamically proven female urinary stress incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use: Yes

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

Concurrence of CDRH, Office of Device Evaluation

David Krone for MxM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091180