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MPATHY MEDICAL DEVICES, LTD.
OMNISURE URETHRAL SLING
SPECIAL 510(K) NOTIFICATION

15. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

AUG 12 2009

SUBMITTER	Ms Melissa Peloquin Director of Office Administration Mpathy Medical Devices Inc. 175 Paramount Drive Raynham, MA 02767
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	22 July 2009
CLASSIFICATION	Surgical Mesh (Product Code OTN) is a Class II device per 21 CFR 878.3300
COMMON NAME	Surgical Mesh
PROPRIETARY NAME	Omnisure™ Urethral Sling
PREDICATE DEVICE	K073647 – Minitape® Extra Urethral Sling (Mpathy Medical Devices) K011251, K013355, K021263 & K020663 - SPARC Sling System (American Medical Systems) K974098 - TVT (Ethicon) K091180 - Minitape® O Urethral Sling (Mpathy Medical Devices)
DEVICE DESCRIPTION	Omnisure™ Urethral Sling is a surgical 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. The proprietary mesh is supplied along with ancillary tools for placement of the device. The device is supplied sterile.
INDICATIONS	Omnisure™ Urethral Sling is indicated for the surgical treatment of urodynamically proven female urinary stress incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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TECHNOLOGICAL CHARACTERISTICS	Omnisure™ Urethral Sling has the same intended use, general design, material and fundamental scientific technology as the predicate Minitape Extra Urethral Sling (K073647).
TESTING	The components of the Omnisure™ device are substantially equivalent to the predicate Minitape® Extra device (K073647), which has been subjected to biocompatibility and mechanical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mpathy Medical Devices, Ltd.
% Mpathy Medical Devices, Inc.
Ms. Melissa Peloquin
Director of Office Administration
175 Paramount Drive
RAYNHAM MA 02767

SEP 28 2012

Re: K092203
Trade/Device Name:
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: July 22, 2009
Received: July 22, 2009

Dear Ms. Peloquin:

This letter corrects our substantially equivalent letter of August 12, 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.

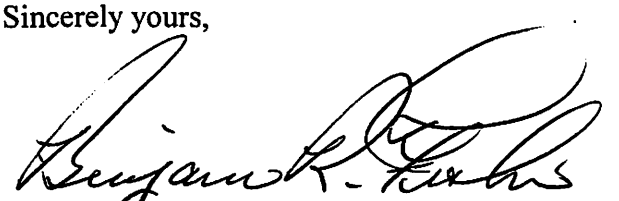
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,



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

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MPATHY MEDICAL DEVICES, LTD.
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14. STATEMENT FOR INDICATIONS FOR USE

510(k) Number: _____

Device Name: Omnisure™ Urethral Sling

Indications for Use: Omnisure™ 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 Krause for MKM

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

510(k) Number K092203