MAY 17 2004

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510(k) Summary
For the Sofradim Production
URETEX SUP® Pubourethral Sling and Instruments

1. SPONSOR

Sofradim Production
116 avenue du Formans
01600 Trevoux
France

Contact: Patrice Becker
Telephone: 33 (0)4 74 08 90 00
Facsimile: 33 (0)4 74 08 90 02

2. DEVICE NAME

Proprietary Name:	URETEX SUP® Device
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh

3. PREDICATE DEVICES

Ethicon TVT	K974098
Sofradim Parietene® Meshes	K991400
Mentor Sling	K980483

4. DEVICE DESCRIPTION

The URETEX® SUP Pubourethral Sling is used in gynecological procedures for the treatment of stress incontinence. The URETEX® SUP device is made from polypropylene sealed monofilament stitches (tape). It is composed of an insertion instrument, connector, sheath, and the pubourethral implant. The insertion instrument consists of a stainless steel needle with PVC tubing.

5. INTENDED USE

The URETEX® SUP device is indicated for the treatment of stress urinary incontinence in women.

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6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The URETEX® SUP Polypropylene Mesh is substantially equivalent to the T.V.T. Ethicon Prolene Pubourethral Tape, the Sofradim Parietene® Mesh, and the Mentor Sling Device.

The URETEX® SUP Polypropylene Mesh and the TVT device have the same intended use in that they are all used for treatment of stress urinary incontinence as well as reinforcement of tissue during surgical repair.

The URETEX SUP, the TVT Ethicon (Prolene® mesh), the Mentor Sling and the Parietene® Polypropylene Mesh are all made from polypropylene sealed monofilament stitches. All of the devices are single-use only.

7. PERFORMANCE TESTING

Testing was performed in accordance with ISO standards. The density, thickness, elongation, breaking strength, tear resistance, burst resistance, and tensile strength were evaluated to determine the performance characteristics of the Pubourethral Sling. All of the testing was performed using the URETEX® SUP Sling, the Ethicon Prolene®, and the Sofradim Parietene® predicate devices for comparative purposes. The test results showed that the Sofradim and predicate devices were similar in performance characteristics.

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

Sofradim Production
% Ms. Mary McNamara-Cullinane
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

SEP 28 2012

Re: K041176
Trade/Device Name: URETEX® TO Trans-Obturator Urethral Support System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: May 4, 2004
Received: May 5, 2004

Dear Ms. McNamara-Cullinane:

This letter corrects our substantially equivalent letter of May 17, 2004.

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.

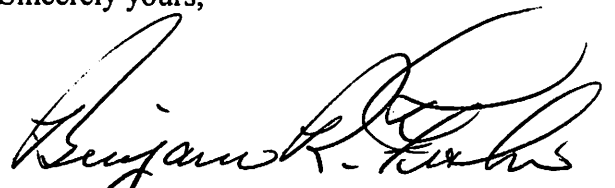
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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

K041176

Indications for Use

510(k) Number (if known):

Device Name: URETEX® TO Trans-Obturator Urethral Support System

Indications For Use:

The URETEX® TO Trans-Obturator Urethral Support System is indicated for the treatment of female stress urinary incontinence from urethral hyper mobility and/or intrinsic sphincter deficiency.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K041176