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510(k) Summary
for
UGYTEX® Mesh

1. SPONSOR

Sofradim Production
116 Avenue du formans
01600 Trevoux
France

Contact: Christophe Cosson
Telephone: 33 (0)4 74 08 90 00
Facsimile: 33 (0)4 74 08 90 02

2. DEVICE NAME

Proprietary Name: UGYTEX® Mesh
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh

3. PREDICATE DEVICES

Sofradim Parietex® Composite Mesh	K002699
Sofradim Parietene® Mesh	K991400
Ethicon Gynemesh Prolene Soft	K013718

4. DEVICE DESCRIPTION

The UGYTEX Mesh is a surgical mesh used during open or laparoscopic procedures. The UGYTEX Mesh is made from polypropylene and a collagen based hydrogel component. The hydrophilic collagen film does not affect the physical performance characteristics of the mesh but serves to temporary separate the mesh from adjacent organs to minimize visceral attachment to the mesh, which may occur during the healing process. The UGYTEX Mesh is offered in several sizes and shapes to accommodate the type and approach of the operation.

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5. INTENDED USE

The UGYTEX Mesh is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Sofradim UGYTEX Mesh is composed of two biocompatible components: polypropylene mesh and a hydrophilic collagen film. The polypropylene material used in the UGYTEX Mesh is identical to the polypropylene used in Sofradim's Parietene polypropylene mesh, which received FDA marketing clearance under K991400. The UGYTEX Mesh is constructed of reduced diameter monofilament fibers, knitted into a design identical to the Parietene polypropylene mesh. This mesh with large pores allows fast tissue ingrowth and exhibits more flexibility than standard Parietene mesh. The collagen component of the Sofradim UGYTEX Mesh is derived from a Porcine source and meets all the requirements in the FDA collagen guidance documents. In addition, the Sofradim mesh and predicate devices are available in various sizes and shapes to accommodate different surgical procedures and/or surgeon's choice.

7. PERFORMANCE TESTING

Biocompatibility testing demonstrates that the materials used in the Sofradim UGYTEX Mesh are biocompatible and safe for its intended use.

Testing was performed to determine the performance characteristics of the Mesh. The density, thickness, elongation, breaking strength, tear resistance, burst resistance, and tensile strength were all evaluated. The test results showed that the Sofradim UGYTEX Mesh has similar performance characteristics as previously cleared surgical meshes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2004

Sofradim Production
c/o Ms. Mary McNamara-Cullinane
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K033376
Trade/Device Name: UGYTEX® Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: October 21, 2003
Received: October 23, 2003

Dear Ms. McNamara-Cullinane:

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.

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 Office of Compliance at (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033376

510(k) Number (if known): **K033376**

Device Name: UGYTEX® Mesh

Indications for Use:

The UGYTEX Mesh is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K033376