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AUG 5 - 2005

510(k) Summary
for
UGYTEX® Dual Knit 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® Dual Knit Mesh
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh

3. PREDICATE DEVICES

Sofradim UGYTEX® Mesh K033376

4. DEVICE DESCRIPTION

The Sofradim UGYTEX® Dual Knit Mesh is a monofilament, polypropylene mesh coated in the central portion with an absorbable hydrophilic film of porcine collagen. The nonabsorbable, polypropylene mesh provides a long-term reinforcement for support structures. The hydrophilic film minimizes visceral attachment to the mesh which may occur during the healing process.

The UGYTEX Dual Knit Mesh will be offered in various configurations which may include a rectangular sheet, anterior repair system and posterior repair system.

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5. INDICATIONS FOR USE

The UGYTEX® Dual Knit 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 UGYTEX® Dual Knit Mesh is substantially equivalent in material, function, performance and design to the predicate UGYTEX® Mesh.

7. PERFORMANCE TESTING

The appropriate testing was performed to determine the performance characteristics of the mesh. The test results showed that the Sofradim UGYTEX® Dual Knit Mesh is substantially equivalent to the predicate device.

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
% Pamela Papineau, RAC
Consultant to Sofradim Production
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
AYER MA 01432

SEP 28 2012

Re: K051503
Trade/Device Name: UGYTEX® Dual Knit Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP, PAI, OTO, PAJ
Dated: June 6, 2005
Received: June 7, 2005

Dear Ms. Papineau:

This letter corrects our substantially equivalent letter of August 5, 2005.

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

K051503

510(k) Number (if known):

Device Name: UGYTEX® Dual Knit Mesh

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Prescription Use __X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K051503