APR 2 9 2004

K040998

510(k) Summary
for
PARIETEX® COMPOSITE 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: PARIETEX® COMPOSITE Mesh
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh

3. PREDICATE DEVICES

Sofradim PARIETEX®COMPOSITE Meshes, K002699
Sofradim UGYTEX® Mesh, K033376

4. DEVICE DESCRIPTION

The PARIETEX® COMPOSITE Mesh is a surgical mesh used during open (laparotomy) procedures or during laparoscopic procedures. The PARIETEX® COMPOSITE Mesh is made from polyethylene terephtalate (polyester) and a collagen-based hydrogel component. The hydrophilic collagen film does not affect the physical performance characteristics of the mesh but serves to separate the coated side of the mesh from underlying tissues to minimize tissue attachment and ingrowth. The PARIETEX® COMPOSITE Mesh is offered in several sizes and shapes to accommodate the type and approach of the surgical procedure.

5. INTENDED USE

The PARIETEX® COMPOSITE Mesh is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair, and parietal (i.e., pertaining to the walls) reinforcement of tissues. The non-resorbable three-dimensional polyester mesh provides long-term reinforcement of soft tissues. On the opposite side, the resorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Sofradim PARIETEX COMPOSITE (PCO) meshes are identical to the current PARIETEX® COMPOSITE (PCO) (K002699) meshes with the exception of a modification in the origin of the collagen of the hydrophilic film. In the current PCO meshes, the oxidized collagen is obtained from bovine dermis. In the proposed PCO meshes, the collagen is obtained from porcine dermis.

7. PERFORMANCE TESTING

The polyester mesh material used is not modified and remains the same as that described in the current PCO file (K002699). A study was conducted and demonstrated that there was no statistically significant difference between the test groups in tissue attachment. Both the porcine and bovine products were successful at minimizing tissue attachments. A histological analysis was also performed using randomly selected animals. Additionally, there was no difference in the cellular inflammatory reaction to the two products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2004

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

Re: K040998
Trade/Device Name: Sofradim PARIETEX® COMPOSITE (PCO) Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: April 16, 2004
Received: April 19, 2004

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,

for Miriam C. Provost

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

K040998

Indications for Use

510(k) Number (if known):

Device Name: Sofradim PARIETEX®COMPOSITE (PCO) Mesh

Indications for Use:

The PARIETEX® Composite Mesh is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair, and parietal (i.e. pertaining to the walls) reinforcement of tissues. The non-resorbable three-dimensional polyester mesh provides long-term reinforcement of soft tissues. On the opposite side, the resorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

Prescription Use ___X___ 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 K040998