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# 510(k) Summary
# for
# PARIETEX COMPOSITE
# PCO-OS and PCO-OB 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 PCO-OS and PCO-OB Mesh
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh

## 3. PREDICATE DEVICES

Sofradim PARIETEX COMPOSITE Meshes, K002699 and K040998

Bard Composix Kugel Mesh, K003323

## 4. DEVICE DESCRIPTION

The PARIETEX COMPOSITE PCO-OS and PCO-OB Meshes are surgical meshes used during open (laparotomy) procedures or during laparoscopic procedures. The meshes are made from polyethylene terephtalate (polyester) and a collagen-based hydrogel component. The hydrophilic collagen film does not affect the physical performance characteristics of the meshes but serves to separate the coated side of the meshes from underlying tissues to minimize tissue attachment and ingrowth. The

PCO-OB and PCO-OS Meshes are offered in several sizes and shapes to accommodate the type and approach of the surgical procedure.

The Sofradim PCO-OS and PCO-OB Meshes are identical to the predicate PARIETEX COMPOSITE (PCO) meshes (K002699 and K040998) with the exception of the addition of a bi-dimensional textile flap to the current three-dimensional reinforcement on the PCO Mesh. This flap is manufactured and sewn to the three-dimensional textile with the same polyester yarn as described in the predicate PCO meshes as well as other PARIETEX meshes (K982532 and K003990). The bidimensional flap has been added to the parent PCO Meshes to ease placement and fixation of the mesh during open surgery.

## 5. INTENDED USE

The PARIETEX COMPOSITE PCO-OS and PCO-OB Meshes are used for the reinforcement of tissues during surgical repair. They are indicated for the treatment of incisional hernias, abdominal wall repair, and parietal (i.e., pertaining to the walls) reinforcement of tissues. The non-resorbable polyester meshes provide long-term reinforcement of soft tissues. On the opposite side, the resorbable hydrophilic film minimizes tissue attachment to the meshes in case of direct contact with the viscera.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The PCO-OS and PCO-OB Meshes are identical to the predicate PCO meshes with the exception of the addition of a bi-dimensional textile flap to the current three-dimensional reinforcement. This flap is manufactured and sewn to the original three-dimensional textile with the same polyester yarn as described for the predicate PCO meshes. The absorbable hydrophilic film is unchanged.

## 7. PERFORMANCE TESTING

The polyester mesh material used is not modified and remains the same as that described in the current PCO file (K002699(textile) and K040998-(collagen source)). A study was conducted and demonstrated that the sewing of the additional flap does not adversely affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

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

Re: K050187
Trade/Device Name: PARIETEX® COMPOSITE PCO-OS and PCO-OB Meshes
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: January 25, 2005
Received: January 27, 2005

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 (240) 276-0115. 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/industry/support/index.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

K050187

## Indications for Use

510(k) Number (if known):

Device Name: PARIETEX® COMPOSITE PCO-OS and PCO-OB Meshes

Indications for Use:

The PCO-OS and PCO-OB meshes are used for the reinforcement of tissues during surgical repair. They are indicated for the treatment of incisional hernias, abdominal wall repair, and parietal (i.e. pertaining to the walls) reinforcement of tissues. The non-resorbable 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** K050187