

K110663

1 of 2

510(k) Summary of Safety and Effectiveness

AUG 1 1 2011

Submitter Information

Name: Sofradim Production
Address: 116 avenue du Formans
01600 Trevoux
France

Phone number: +33 (0) 4 74 08 90 00
Fax number: +33 (0) 4 74 08 90 02
Establishment Registration: 9615742
Name of contact person: James McMahon
Manager, Regulatory Affairs
Covidien
15 Crosby drive
Bedford, MA 01730 USA
Phone: (781) 839 1787

Date prepared: March 4, 2011

Name of device

Trade or proprietary name: PARIETEX™ Optimized Composite Mesh
Common or usual name: Surgical Mesh
Classification name: Mesh, Surgical, Polymeric

Classification panel: General and Plastic Surgery (79)

Regulation: 21 CFR 878.3300

Product Code: FTL

Legally marketed devices to

which equivalence is claimed: PARIETEX™ Composite Mesh (K002699 and K040998)
Dermalon® suture (K930586)
BIOMESH® CA.B.S.'Air® (K072962)

Reason for 510(k) submission: To introduce the PARIETEX™ Optimized Composite mesh which is made from a three-dimensional multifilament polyester knit covered with an absorbable, continuous and hydrophilic film on one side. The multifilament polyester material provides long term wall reinforcement while the hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera. One or many non-absorbable color monofilament threads are pre-tied to the three-dimensional mesh to facilitate placement and fixation of the mesh. The proposed PARIETEX™ Optimized Composite Mesh has been improved compared to the predicate devices as the knitting textile has been modified to obtain a higher mechanical resistance of the mesh and the collagen film formulation has been changed to get a film more resistant to handling.

K110663
2 of 2

Device description: PARIETEX™ Optimized Composite Mesh is available in rectangular and round shape. This device is made out of a three-dimensional multifilament polyester knit for wall reinforcement, covered with an absorbable, continuous and hydrophilic film on one of its sides. This film is made up of collagen from porcine origin and glycerol, and extends 5 mm over the edge of the reinforcement. One or many non-absorbable color monofilaments are tied to the three-dimensional mesh

Intended use of the device: The PARIETEX™ Optimized Composite Mesh is used for the reinforcement of tissues during surgical repair.

Indications for use: 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-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

Summary comparing the technological characteristics of the subject and predicate devices: The subject PARIETEX™ Optimized Composite Mesh is equivalent to the predicate devices PARIETEX™ Composite Mesh (K002699, K040998) and Dermalon® suture (K981532) in terms of its technological characteristics and material. The three-dimensional multifilament polyester knit and and monofilament sutures are identical to the predicates. No major technological changes are proposed to the currently marketed devices PARIETEX™ Composite Mesh and Dermalon® suture in this submission.

Performance data: Bench testing was conducted in accordance with FDA's guidance for the Preparation of a Premarket Notification Application for Surgical Mesh to evaluate the performance characteristics of the proposed PARIETEX™ Optimized Composite Mesh. Bench testing for Surgical Mesh included physical characterization and extensive mechanical performance testing with comparison to the predicate PARIETEX™ Composite Mesh. These tests demonstrated improvement of mechanical properties of proposed device versus predicate.

Confirmation tests on Dermalon® threads were conducted and demonstrated the compliance with the Tensile Strength Suture US Monograph. This tests confirmed Dermalon ability to fill the suture function.

In-vivo performance testing on representative animal model was conducted in comparison with predicate to demonstrate the collagen film minimizes visceral attachment to the mesh. The results demonstrated the performance of the collagen film of PARIETEX™ Optimized Composite Mesh was equivalent to the predicate.

The results of the nonclinical and pre-clinical tests demonstrate that the device performs as well as or better than the legally marketed predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

Sofradim Production
% Covidien
Mr. James McMahon
15 Crosby Drive
Bedford, Massachusetts 01730

AUG 11 2011

Re: K110663
Trade/Device Name: PARIETEX™ Optimized Composite Mesh (PCO-FX references)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: August 3, 2011
Received: August 5, 2011

Dear Mr. McMahon:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

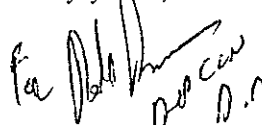
Page 2 - Mr. James McMahon

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" (21CFR 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,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over a faint, larger version of the typed name below it.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K110663

Device Name: PARIETEX™ Optimized Composite Mesh (PCO-FX references)

Indications For Use:

The PARIETEX™ OPTIMIZED 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-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

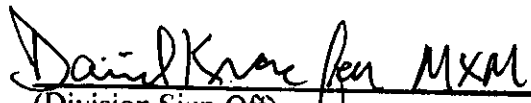
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110663