510(k) Summary

JUN 13 2012

Submitter Information

Name:	Sofradim Production (subsidiary of Covidien llc)
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: (US Agent)	James McMahon Senior Manager, Regulatory Affairs Covidien 15 Crosby Drive Bedford, MA 01730 USA Phone: (781) 839 1787
Date prepared:	**June 11, 2012**

Name of device

Trade or proprietary name:	Parietex™ Composite Ventral Patch
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 (K040998) Bard Ventralex® Patch (K021736 and K024008)
Reason for 510(k) submission:	To introduce the Parietex™ Composite Ventral Patch which is a dual facing mesh, covered with an absorbable collagen film.
Device description:	Parietex™ Composite Ventral Patch is available as a round shape. It is a dual facing mesh composed of a non-absorbable three-dimensional monofilament polyester textile for abdominal wall reinforcement covered by a bioabsorbable hydrophilic collagen film to minimize visceral attachment. A fixation system composed of four flaps made out of a bidimensional monofilament polyester textile and two removable handles completes the device. This fixation system and the three-dimensional reinforcement textile are assembled with two poly(glycolide-co-L-lactide) (PGLA) expanders. This system facilitates placement and fixation of the mesh.

Intended use of the device:

The Parietex™ Composite Ventral Patch is used for the reinforcement of soft tissues during surgical repair.

Indications for use:

The Parietex™ Composite Ventral Patch is used for the reinforcement of soft tissues during surgical repair. It is indicated for the treatment of ventral defects (primary and incisional hernias). The three-dimensional non absorbable monofilament polyester mesh provides long term reinforcement of soft tissues. 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:

The Parietex™ Composite Ventral Patch is substantially equivalent to the predicate devices, Parietex™ Composite Mesh (K040998) and Bard Ventralex® Patch (K021736 and K024008), in terms of its technological characteristics and material.

The Parietex™ Composite Ventral Patch is equivalent to the polyester textile and hydrophilic collagen film performance as the predicate Parietex™ Composite Mesh (K040998). In addition, the mechanical performance of the fixation polyester flap is also equivalent to the polyester textile of the predicate Parietex™ Composite Mesh (K040998). The proposed Parietex™ Composite Ventral Patch is substantially equivalent to the predicate Bard Ventralex® Patch (K021736 and K024008) in assembly strength.

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™ Composite Ventral Patch. Bench testing included :

- Textile characterizations which demonstrate that the mechanical performance of the textiles are equivalent to the predicate Parietex™ Composite Mesh (K040998),
- Traction testing to demonstrate the equivalency of the assembly tensile strength of the mesh compared to the predicate Bard Ventralex® Patch (K021736 and K024008).

In vivo performance testing on a representative animal model was conducted in comparison with predicate to demonstrate the collagen film minimizes attachment to the mesh. The results demonstrates that the collagen film performance of Parietex™ Composite Ventral Patch is equivalent to the predicate Parietex™ Composite Mesh (K040998).

The results of the bench and preclinical tests demonstrate that the device is substantially equivalent to its predicate devices, Parietex™ Composite Mesh (K040998) and the Bard Ventralex® Patch (K021736 and K024008).

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

JUN 13 2012

Sofradim Production
% Surgical Devices, A Global Bus of Covidien
Mr. James McMahon
Senior Manager, Regulatory Affairs
15 Crosby Drive
Bedford, Massachusetts 01730

Re: K120506
Trade/Device Name: PARIETEX ™ Composite Ventral Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL, OXJ
Dated: May 11, 2012
Received: May 14, 2012

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 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,

for

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): K120506

Device Name: PARIETEX™ Composite Ventral Patch

Indications For Use:

The PARIETEX™ composite ventral patch is used for the reinforcement of soft tissues during surgical repair. It is indicated for the treatment of ventral defects (primary and incisional hernias). The three-dimensional non-absorbable monofilament polyester mesh provides long term reinforcement of soft tissues. The absorbable 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 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 K120506