# 510(k) Summary of Safety and Effectiveness

AUG 13 2008

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| SUBMITTER: | Sofradim Production<br>116, avenue du formans<br>01600 Trevoux, France<br>Phone: 33 0 4 74 08 90 00 |
| CONTACT PERSON: | Sharon Alexander<br>Senior Associate, Regulatory Affairs<br>Covidien<br>60 Middletown Avenue<br>North Haven, CT 06473 USA<br>Phone: (203) 492-6060 |
| DATE PREPARED: | July 17, 2008 |
| TRADE/PROPRIETARY NAME: | PARIETEX™ COMPOSITE Mono PM Mesh |
| COMMON/USUAL NAME: | Surgical Mesh |
| CLASSIFICATION NAME: | Mesh, Surgical, Polymeric |
| PREDICATE DEVICE: | PARIETEX™ COMPOSITE (PCO) Mesh (K040998) |
| DEVICE DESCRIPTION: | PARIETEX™ COMPOSITE Mono PM Mesh is made from a monofilament polyester fabric, covered with an absorbable hydrophilic film. The meshes are available in two different designs. Both are round in shape.<br>The first design is made from a three-dimensional monofilament polyester fabric and has a circular opening in the center. It is completely covered on one side with an absorbable hydrophilic film made of collagen from porcine origin, polyethylene glycol and glycerol.<br>The second design is made from a three dimensional monofilament polyester fabric with a two-dimensional monofilament polyester central band. One side of the second design is completely covered with the hydrophilic film. On the opposite side, only the two dimensional central band is coated with the absorbable hydrophilic film.<br>On both designs the film extends 5 mm over the external edge of the reinforcement, and also extends around the internal edge of the circular opening if any. |
| INTENDED USE: | The PARIETEX™ COMPOSITE Mono PM Mesh is indicated for the reinforcement of soft tissues during surgical repair, and specifically for the repair of parastomal hernias. The non-absorbable polyester mesh provides long term reinforcement of soft tissues. The absorbable hydrophilic film minimizes tissue attachment to the mesh when in direct contact with the viscera. |

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| TECHNOLOGICAL CHARACTERISTICS: | The technological characteristics of PARIETEX™ COMPOSITE Mono PM Mesh are similar to those of the predicate device. Like the predicate, PARIETEX™ COMPOSITE Mono PM Mesh is manufactured from two components: polyester knitted mesh and a hydrophilic collagen film. |
| MATERIALS: | PARIETEX™ COMPOSITE Mono PM Mesh is comprised of materials that have been evaluated for biocompatibility in accordance with ISO 10993-1. |
| PERFORMANCE DATA: | Bench testing has been conducted to evaluate the performance characteristics of PARIETEX™ COMPOSITE Mono PM Mesh. Results of mechanical properties testing show that PARIETEX™ COMPOSITE Mono PM Mesh has similar performance characteristics to the predicate PARIETEX™ COMPOSITE Mesh. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sofradim Production
% Covidien
Ms. Sharon Alexander
Senior Regulatory Affairs Associate
60 Middletown Avenue
North Haven, Connecticut 06473

AUG 13 2008

Re: K081126
Trade/Device Name: PARIETEX™ COMPOSITE Mono PM Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: August 8, 2008
Received: August 11, 2008

Dear Ms. Alexander:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

# Indications For Use

510(k) Number (if known): _____

Device Name: PARIETEX™ COMPOSITE Mono PM Mesh

Indications For Use:

The PARIETEX™ COMPOSITE Mono PM Mesh is indicated for the reinforcement of soft tissues during surgical repair, and specifically for the repair of parastomal hernias. The non-absorbable polyester mesh provides long term reinforcement of soft tissues. The absorbable hydrophilic film minimizes tissue attachment to the mesh when in 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 General, Restorative,**
**and Neurological Devices**

K081126

**510(k) Number**