# 510(k) Summary of Safety and Effectiveness

MAY 28 2008

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| SUBMITTER: | Sofradim Production<br>116, avenue du formans<br>01600 Trevoux, France<br>Phone: 33 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: | April 10, 2008 |
| COMMON/USUAL NAME: | Surgical Mesh |
| CLASSIFICATION NAME: | Mesh, Surgical, Polymeric |
| PREDICATE DEVICE(S): | PARIETEX™ Mesh (K982532)<br>PARIETEX™ Mesh TET1208D and TET1409D (K003990)<br>PREVADH™ Mesh (K073287)<br>TICRON™ Suture (K930591) |
| DEVICE DESCRIPTION: | PARIETEX™ PROGRIP™ Mesh will be available in 2 shapes:<br>▪ Pre-cut, elliptic slit mesh with a self–gripping overlapping flap. Right or left side.<br>▪ Rectangular simple mesh.<br>These meshes and the overlapping flaps of the pre-cut versions are made from knitted monofilament polyester with monofilament polylactic acid (PLA) resorbable pins on one side. The PLA pins facilitate placing, positioning and fixation of the overlapping flap and the meshes to the surrounding tissue. A colored yarn marker on the medial edge of the pre-cut mesh helps in orientation. |
| INTENDED USE: | PARIETEX™ PROGRIP™ Mesh is indicated for inguinal and incisional hernia repair. |
| TECHNOLOGICAL CHARACTERISTICS: | The technological characteristics of PARIETEX™ PROGRIP™ Mesh are similar to those of the predicate devices. PARIETEX™ PROGRIP™ meshes are manufactured with knitted monofilament polyester and monofilament polylactic acid resorbable pins. |
| MATERIALS: | PARIETEX™ PROGRIP™ Mesh is comprised of materials that have been evaluated in accordance with ISO 10993-1 and/or USP standards. |

PERFORMANCE DATA:

Bench and animal testing has been conducted to evaluate the performance characteristics of PARIETEX™ PROGRIP™ Mesh. Results of mechanical property testing show that PARIETEX™ PROGRIP™ has similar performance characteristics to the predicate PARIETEX™ Mesh.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2008

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

Re: K081050
Trade/Device Name: PARIETEX™ PROGRIP™ Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: April 10, 2008
Received: April 14, 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

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): K081050

**Device Name: PARIETEX™ PROGRIP™ Mesh**

Indications for Use:

PARIETEX™ PROGRIP™ Mesh is indicated for inguinal and incisional hernia repair.

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)

Neil R.P. Ogden for MKM

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K081050