## 510(k) Summary of Safety and Effectiveness

K101197

MAY - 5 2010

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| SUBMITTER: | Sofradim Production<br>116, avenue du formans<br>01600 Trevoux, France<br>Phone: 33 04 74 08 90 00 |
| CONTACT PERSON: | Sharon Alexander<br>Associate Manager, Regulatory Affairs<br>Covidien<br>60 Middletown Avenue<br>North Haven, CT 06473 USA<br>Phone: (203) 492-6060 |
| DATE PREPARED: | April 26, 2010 |
| TRADE/PROPRIETARY NAME: | PARIETENE PROGRIP™ Mesh |
| COMMON/USUAL NAME: | Surgical Mesh |
| CLASSIFICATION NAME: | Mesh, Surgical, Polymeric |
| PREDICATE DEVICE(S): | PARIETEX Progrip™ Mesh (K081050)<br>PARIETENE™ Mesh (K991400)<br>PARIETEX™ TET Mesh (K003990) |
| DEVICE DESCRIPTION: | PARIETENE PROGRIP™ Mesh is available in 2 forms:<br>• Pre-cut, elliptic slit mesh with 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 of knitted monofilament polypropylene with polylactic acid (PLA) resorbable pins on one of the sides. The PLA pins facilitate placement, positioning and fixation of the overlapping flap and the mesh to the surrounding tissue. A colored yarn marker on the medial edge of the pre-cut mesh helps orientation. |
| INDICATION: | PARIETENE PROGRIP™ Mesh is indicated for inguinal and incisional hernia repair. |
| TECHNOLOGICAL CHARACTERISTICS: | PARIETENE PROGRIP™ meshes are made with knitted monofilament polypropylene and monofilament polylactic acid resorbable pins. The intended use and fundamental technology of PARIETENE PROGRIP™ Mesh are equivalent to that of the predicate PARIETEX PROGRIP™. |
| MATERIALS: | PARIETENE PROGRIP™ Mesh is comprised of biocompatible materials that are in compliance with ISO 10993-1 and/or USP standards. |
| PERFORMANCE DATA: | Bench testing has been conducted to evaluate the performance characteristics of PARIETENE PROGRIP™. Testing has shown that the PARIETENE PROGRIP™ is equivalent in performance characteristics to the predicate PARIETEX PROGRIP™. |

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

Sofradim Production
% Covidien – Div. of Tyco Healthcare Group LP
Ms. Sharon Alexander
Associate Manager, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

MAY - 5 2010

Re: K101197
Trade/Device Name: Parietene Progrip™ Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: April 28, 2010
Received: April 28, 2010

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. 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,

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): K101197

Device Name:

PARIETENE 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 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

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



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