510(k) Summary of Safety and Effectiveness

K072951

1/2

DEC 19 2007

SUBMITTER:	Sofradim Production 116, avenue du Formans 01600 Trevoux, France Tel. No.: (33) 04 74 08 90 00
CONTACT PERSON:	Sharon Alexander Senior Associate, Regulatory Affairs Covidien 150 Glover Avenue Norwalk, CT 06856 USA Tel. No.: (203) 492-6060
DATE PREPARED:	October 17, 2007
TRADE/PROPRIETARY NAME:	Parietene™ Duo Polypropylene Mesh Parietene™ Quadra Polypropylene Mesh
COMMON/USUAL NAME:	Surgical Mesh
CLASSIFICATION NAME:	Mesh, Surgical, Polymeric
PREDICATE DEVICE(S):	UGYTEX™ Dual Knit Mesh (K051503) Parietene™ Polypropylene Mesh (K991400)
DEVICE DESCRIPTION:	Parietene™ Duo and Parietene™ Quadra are monofilament polypropylene prolapse repair meshes. The nonabsorbable, polypropylene mesh provides a long-term reinforcement for support structures. Parietene™ Duo Polypropylene Mesh is a pre-shaped mesh for posterior prolapse repair. Parietene™ Quadra Polypropylene Mesh is a pre-shaped mesh for anterior prolapse repair. Parietene™ Duo and Parietene™ Quadra meshes have a soft knit in the central section for compliant organ support and a strong knit in the lateral sides to provide strength for tension-free fixation of the mesh.
INTENDED USE:	Parietene™ Duo and Parietene™ Quadra Polypropylene Meshes are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.
TECHNOLOGICAL CHARACTERISTICS:	The technological characteristics, design and materials of the meshes are substantially equivalent to the predicate UGYTEX™ Dual Knit Mesh.
MATERIALS:	Parietene™ Duo and Parietene™ Quadra Polypropylene Meshes are comprised of materials that have been evaluated for biocompatibility for their intended patient contact profile according to ISO 10993-1 and/or USP standards.

PERFORMANCE DATA: Testing was conducted to determine the performance characteristics of the subject meshes. The results demonstrate that the Parietene™ Duo and Parietene™ Quadra Polypropylene Meshes are substantially equivalent to the predicate UGYTEX™ Dual Knit Mesh.

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
% Ms. Sharon Alexander
Senior Associate, Regulatory Affairs
Covidien
150 Glover Avenue
NORWALK CT 06856

SEP 28 2012

Re: K072951
Trade/Device Name: Parietene™ Duo and Parietene™ Quadra Polypropylene Meshes
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP, OTO
Dated: November 26, 2007
Received: November 27, 2007

Dear Ms. Alexander:

This letter corrects our substantially equivalent letter of December 19, 2007.

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 (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 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.

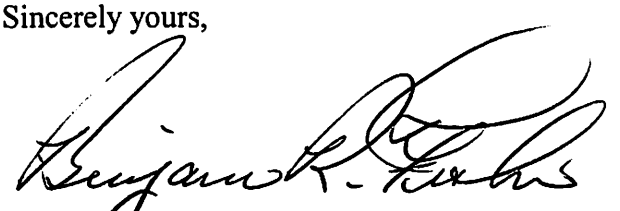
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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" (21 CFR 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,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K072951

Indications For Use

510(k) Number (if known): _____

Device Name: Parietene™ Duo and Parietene™ Quadra Polypropylene Meshes

Indications for Use:

Parietene™ Duo and Parietene™ Quadra Polypropylene Meshes are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

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

510(k) Num K072951