K090858

510(k) Summary of Safety and Effectiveness

MAY - 6 2009

SUBMITTER:	Sofradim Production 116, avenue du formans 01600 Trevoux, France Phone: 33 0 4 74 08 90 00
CONTACT PERSON:	Angela L. Bunn, RAC Associate Manager, Regulatory Affairs Covidien 60 Middletown Avenue North Haven, CT 06473 USA Phone: (203) 492-5325
DATE PREPARED:	March 27, 2009
TRADE/PROPRIETARY NAME:	PARIETEX™ - Monofilament Polyester Mesh
COMMON/USUAL NAME:	Surgical Mesh
CLASSIFICATION NAME:	Mesh, Surgical, Polymeric
PREDICATE DEVICE(S):	MERSILENE™ (Ethicon) (Preamendment device, marketed prior to May 28, 1976) PARIETEX™ COMPOSITE Mono PM Mesh (K081126)
DEVICE DESCRIPTION:	PARIETEX™ - Monofilament Polyester Mesh is made out of a non-absorbable bi-dimensional monofilament polyester knitting and is available in rectangular shape.
INTENDED USE:	PARIETEX™ - Monofilament Polyester Mesh is indicated for inguinal and ventral hernia repair.
TECHNOLOGICAL CHARACTERISTICS:	The technological characteristics of PARIETEX™ - Monofilament Polyester Meshes are similar to those of the predicate devices. The proposed device is similar to the predicate device (PARIETEX™ Composite Mono PM Mesh) in that the base materials of polyester are the same. In regards to other technological aspects the predicate device (MERSILENE™) are similar in form and function.
MATERIALS:	PARIETEX™ - Monofilament Polyester 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 PARIETEX™ - Monofilament Polyester Mesh. Testing has shown that the PARIETEX™ - Monofilament Polyester Mesh is similar in performance characteristics to the predicate MERSILENE™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2009

Sofradim Production
% Covidien
Ms. Angela L. Bunn, RAC
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K090858
Trade/Device Name: Parietex™ Monofilament Polyester Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: March 27, 2009
Received: March 30, 2009

Dear Ms. Bunn:

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 for
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):

Device Name: Parietex™ Monofilament Polyester Mesh

Indications For Use:

The Parietex™ Monofilament Polyester Mesh is indicated for inguinal and ventral 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)

Daniel Krause

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

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