510(k) Summary

Submitter Information

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Name of contact person: (US Agent)	James McMahon Senior Manager, Regulatory Affairs Covidien 15 Crosby drive Bedford, MA 01730 USA Phone: (781) 839 1787
Date prepared:	June 25, 2012

Name of device

Trade or proprietary name:	Parietex
Common or usual name:	Surgical Mesh
Classification name:	Mesh, Surgical, Polymeric
Classification panel:	General and Plastic Surgery (79)
Regulation:	21 CFR 878.3300
Product Code:	FTL
Legally marketed devices to which equivalence is claimed	Mersilene®, (Ethicon, Johnson & Johnson) Ercylene®, (Davis & Geck) Prolene® , (Ethicon, J & J) Surgipro®, (U.S.S.C.) Marlex®, Visilex@ (Bard - Davol) Atrium® , (Atrium)
Reason for 510(k) submission:	To obtain market clearance on the Parietex Surgical Mesh.
Device description:	Mesh made of Biocompatible, knitted multifibre polyester (PET). Each mesh is supplied sterile and nonpyrogenic in a single-use package.
Intended use of the device:	The Parietex® meshes has the same intended use as the predicate devices: - reinforcement of tissue during surgical repair.

Indications for use:

Parietex™ surgical mesh; slings or pre-cut implants are intended for the repair of Inguinal and Incisional hernias, genito-urinary and rectal prolapses by promontofixation via open abdominal or laparoscopic approach. No applications other than the ones indicated are recommended.

Mechanical Properties:

Comparative Table		Parietex™ (Polyester)	Mersilene® (Polyester)	Prolene® (Polypropylene)	Marlex® (Polypropylene)
Thread Resistance (N)	Chain	68.5	115.2	57	57.2
	Weft	55.4	15.5	74.6	55.8
Tear Resistance (daN)	Chain	3.36	0.64	<0.1	0.66
	Weft	2.78	0.68	4.41	4.03
Breaking resistance (daN)	Chain	39.11	20.53	59.74	43.2
	Weft	63.6	10.04	76.74	56.7

Source : U. Klinge, J. Conze, B. Klosterhalfen, W. Limberg, B. Obolenski, A.P. Öttinger, V. Schumpelick : "Alteration of abdominal wall mechanics after mesh implantation. Experimental alteration of mesh stability. Langenbecks - Archiv für Chirurgie, Band 381 Heft 6, 1996

Performance data:

Biocompatibility Tests
Standard biocompatibility testing was performed according to the ISO 10993 - 1 Standards and FDA requirements.

The device passed all of the following biocompatibility tests:

- Cytotoxicity
- Systemic toxicity
- Intracutaneous toxicity
- Sensitization
- Mutagenicity tests: Ames's test
  Chromosomal aberration
  Sister chromatid exchange
- Implantation tests: Short term implantation
  Long term implantation

All tests were performed according to GLP in an American Laboratory.

Clinical Tests:

"laparoscopic and open abdominal wall reconstruction using PARIETEX® meshes" • Clinical results on 2,700 hernias.
(Paper accepted by "HERNIA" 1998)

Summary:

The authors report a series of 2,445 inguinal hernias and 272 incisional hernias treated between 1993 and 1997 by the insertion of a Parietex® mesh via either a laparoscopic (1,595 procedures) or an open approach (578 procedures). Pain scores and time to return to normal activity were lower in the laparoscopic group

than in the open surgery group (p<0.001). In all of the groups, the average incidence of the total reported events (complications) was around 10 % with no statistical difference. This ratio seemed to compare favorably too previously published reports. Considering inguinal hernias in particular, chronic pains was extremely rare (0.6 % in the laparoscopic group and 0.8 % in the open surgery group). Whatever the approach was, sepsis was also very rare *(1/1526* laparoscopic procedures, *2/380* open operations). These finding& illustrate the local tolerance of the mesh. Recurrence rates were below 1: % with no statistical difference between groups. This retrospective study demonstrates the clinically apparent local tolerance of this type of mesh. Prospective and long term clinical results will be necessary to demonstrate that the optimized short term tolerance of Parietex® mesh will influence the long term functional results.

"Laparoscopic Hernia Repair. Total Extra-Peritoneal Approach • Experience in 1,200 Hernia Repair". Complete Literature Review.
S. Benchetrit, M.D. - Clinique Jeanne d'Arc, LYON (FRANCE).
(Paper accepted by "Surgical Endoscopy" 1998)

Summary:

We report our experience with 1 ,200 consecutive hernia repair by total extraperitoneal approach. Between November 1993 and the end of September 1997, 1,200 hernias have been repaired using the extra-peritoneal approach with a balloon trocar in our center. A balloon dissector was used to dissect the extra-peritoneal space in all patients. A 15 x 10 cm mesh was used. There were no visceral complication, no early recurrence and no sepsis. The follow up was from 3 to 36 months in 90 % of the patients with a low recurrence rate (0.8 %). One patient needed to be reoperated for chronic pain. Return to normal activity was 1-3 days. Surgical cost was compensated by social cost savings due to a shorter hospital stay and a quicker return to normal activity compared to open hernia repair. The early results of this technique experienced during this short study have been encouraging.

Conclusions drawn from the preclinical and clinical testing

The Parietex® meshes are substantially equivalent to the predicate devices because they have the same intended use, very similar indications, principles of operation, and technological characteristics, and any difference in the Parietex® mesh technological characteristics do not raise any new questions of safety or effectiveness.

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

AUG 20 2012

Sofradim Productions
% Mr. Howard M. Holstein
Hogan & Hartson
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K982532
Trade/Device Name: Parietex® Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: December 4, 1998
Received: December 4, 1998

Dear Mr. Holstein:

This letter corrects our substantially equivalent letter of January 20, 1999.

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.

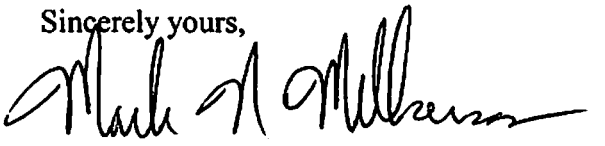
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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

Indication for Use Statement

510(k) Number (if known): K982532

Device Name: Parietex™ ProSup mesh

Indications for Use: PARIETEX™™™ ProSup™ mesh; slings or pre-cut implants are intended for the repair of Inguinal and Incisional hernias, genito-urinary and rectal prolapses by promontofixation via open abdominal or laparoscopic approach. No applications other than the ones indicated are recommended.

Prescription Use __X__ AND/OR Over-the -Counter Use _____
(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 Krone for MM

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

510(k) Number K982532