510(k) Summary of Safety and Effectiveness

JUL 10 2007

SUBMITTER:	Sofradim Production 116, avenue du Formans 01600 Trevoux- France Tel. No.: (33) 04 74 08 90 00
Contact:	Renee Borgesano Manager, Regulatory Affairs (203)492-5325
DATE PREPARED:	June 13, 2007
TRADE/PROPRIETARY NAME:	Parietex® Polyester Mesh
COMMON/USUAL NAME:	Surgical Mesh
CLASSIFICATION NAME:	Surgical Mesh
PREDDICATE DEVICE(S):	Parietex® Polyester Mesh (K982532)
DEVICE DESCRIPTION:	The Parietex® Polyester Mesh will be packaged with an Introducer. Suture loops are attached to the meshes and aide in inserting and removing the mesh from the Introducer.
INTENDED USE:	The Parietex® Polyester Mesh with Introducer is indicated for use in the reinforcement of tissue during surgical repair of inguinal hernias through laparoscopic approach.
TECHNOLOGICAL CHARACTERISTICS:	The technological characteristics, design and materials of the meshes are identical to the predicate device.
MATERIALS:	All components of the Parietex® Polyester Mesh with Introducer are comprised of materials that have passed biocompatibility testing for their intended patient contact profile according to ISO 10993-1 and/or USP standards.
PERFORMANCE DATA:	Bench tests were conducted to demonstrate that the modification to the device did not change the performance when compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sofradim Production
% United States Surgical
Ms. Renee Borgesano
Manager, Regulatory Affairs
150 Glover Avenue
Norwalk, Connecticut 06856

JUL 10 2007

Re: K071629
Trade/Device Name: Parietex® Polyester Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 13, 2007
Received: June 14, 2007

Dear Ms. Borgesano:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

For Director

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071629

Indications For Use

510(k) Number (if known): K071629

Device Name: Parietex® Polyester Mesh

Indications for Use:

The Parietex® Polyester Mesh is indicated for use in the reinforcement of tissue during surgical repair of inguinal hernias through laparoscopic approach.

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) Number K071629