JUL 12 1999

K991400

510(k) Summary
for
Parietene® Polypropylene Mesh

1. SPONSOR

Sofradim Production
197 Avenue Theodore Braun
69400 Villefranche sur Saone
France

Contact: Patrice Becker
Telephone: 33 04 74 60 03 27
Facsimile: 33 04 74 60 03 66

2. DEVICE NAME

Proprietary Name:	Parietene® Polypropylene Mesh
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh

3. PREDICATE DEVICES

Bard-Davol Visilex® Mesh
Atrium Medical Corporation Atrium® Mesh
Sofradim Parietex® Meshes

4. DEVICE DESCRIPTION

The Parietene® Polypropylene Mesh is used during open (laparotomy) procedures or during laparoscopic (transperitoneal or preperitoneal) procedures. The Parietene® Polypropylene Mesh is offered in several sizes and designs to accommodate the type and approach of the operation as described below:

Parietene® Polypropylene Mesh Models PP 0611, 1510, 1515, 2020, and Parietene® PP 3030 can be used during open or laparoscopic procedures. Parietene® PP 1410, and 1510 are used only during laparoscopic procedures.

All of the models are made from polyethylene and are available in various sizes.

The Parietene® Polypropylene Mesh are made from polypropylene sealed monofilament stitches and are offered in square and rectangular shapes with rounded edges. The Parietene® Polypropylene Mesh are fixed to the patient by either staples or sutures.

The Parietene® Polypropylene Mesh Model 1410 contains a thread made from polyvinyl difluorene. This thread is used to keep the mesh folded during insertion through a trocar during laparoscopic procedures. The thread is removed when the mesh has been unfolded in the trocar.

5. INTENDED USE

The Parietene® Polypropylene Mesh is a polypropylene mesh intended for the reinforcement of tissue during surgical repair. It is indicated for inguinal hernias, parietal reinforcement of tissues and abdominal wall repair.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Parietene® Polypropylene Mesh is substantially equivalent to the Sofradim Parietex® Meshes, the Bard-Davol Visilex® Mesh, and the Atrium Medical Corporation Atrium® Mesh. The Parietene® Polypropylene Mesh and the predicate devices have the same intended use in that they are all used for reinforcement of tissue during surgical repair. The Parietene®, Parietex® Polypropylene Mesh and the Atrium Mesh are inserted either through open or laparoscopic methods whereas the Bard-Davol Visilex is inserted laparoscopically only.

The Parietene® Polypropylene Mesh, the Bard-Davol Visilex and Atrium Mesh predicate devices are all made from polypropylene sealed monofilament stitches. The Sofradim Parietex® mesh is made from polyethylene terephtalate. The proposed and predicate devices all offer various sizes and shapes to accommodate different surgical procedures. The proposed Parietene® Mesh is also offered with a lateral slit for cord for easier insertion during laparoscopic procedures. All of the devices are fixed to the patient by either staples or sutures and are single use devices only.

7. PERFORMANCE TESTING

Testing was performed to determine the performance characteristics of the Mesh. The density, thickness, elongation, breaking strength, tear resistance, burst resistance, tensile strength were all evaluated by ITF de LYON, a test laboratory in France. All of the testing was performed using Atrium and Visilex Mesh

predicate devices for comparative purposes and followed ISO standards. The test results showed that the Sofradim and predicate devices were similar in performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 1999

Sofradim Production
c/o Ms. Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K991400
Trade Name: Perietene Polypropylene Mesh
Regulatory Class: II
Product Code: FTL
Dated: April 21, 1999
Received: April 22, 1999

Dear Ms. McNamara:

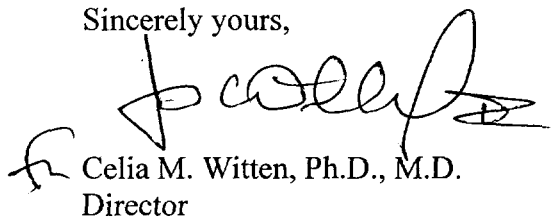
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991400

Device Name: Sofradim Parietene® Polypropylene Mesh

Indications For Use:

The Parietene® Polypropylene Mesh is a polypropylene mesh intended for the reinforcement of tissue during surgical repair. It is indicated for inguinal hernias, parietal reinforcement of tissues and abdominal wall hernia repair.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices K991400
510(k) Number

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)