K073287

510(k) Summary of Safety and Effectiveness

MAR 13 2008

SUBMITTER:	Sofradim Production 116, avenue du formans 01600 Trevoux, France Phone: 33 0 4 74 08 90 00
CONTACT PERSON:	Sharon Alexander Senior Associate, Regulatory Affairs Covidien 60 Middletown Avenue North Haven, CT 06473 USA Phone: (203) 492-6060
DATE PREPARED:	November 20, 2007
TRADE/PROPRIETARY NAME:	PREVADH™ Mesh
COMMON/USUAL NAME:	Surgical Mesh
CLASSIFICATION NAME:	Mesh, Surgical, Polymeric
PREDICATE DEVICE(S):	PARIETEX™ COMPOSITE (PCO) Mesh (K040998) Ethicon, Inc. VICRYL Mesh (K810428) UGYTEX™ Mesh (K033376)
DEVICE DESCRIPTION:	PREVADH™ Mesh is sterile and can be anchored. It has three component layers: one porous side made of lyophilized porcine collagen; one non-porous smooth side made of porcine collagen, polyethylene glycol and glycerol; and a multifilament polylactic acid mesh inserted between the two collagen layers. The porous side is soft and hydrophilic, and combined with the highly porous mesh, allows for fast tissue in-growth. The non-porous smooth side minimizes visceral attachment. The entire PREVADH™ Mesh device resorbs. The porous side is resorbed in less than 1 week and the non-porous smooth side is resorbed in approximately 3 weeks. The multifilament polylactic acid mesh is bioresorbable and offers significant mechanical strength during at least 12 weeks to maintain support throughout the critical healing period.
INTENDED USE:	PREVADH™ mesh is indicated for use when a temporary wound support is required in abdominopelvic surgery. The resorbable hydrophilic film minimizes tissue attachment to the mesh in the case of direct contact with the viscera.
TECHNOLOGICAL CHARACTERISTICS:	The technological characteristics of PREVADH™ Mesh are similar to those of the predicate devices. PREVADH™ Mesh is manufactured from three resorbable components: porous collagen foam, polylactic acid mesh, and a hydrophilic collagen

film. PREVADH™ Mesh is knitted in a design with large pores that allow fast tissue in-growth. The collagen-based components of PREVADH™ Mesh are derived from a porcine source already cleared by FDA for predicate PARIETEX™ COMPOSITE (PCO) Mesh (K040998). As with this predicate PCO Mesh, the hydrophilic collagen film serves to temporarily separate the mesh from adjacent organs to minimize visceral attachment to the mesh which may occur during the healing process.

MATERIALS:

PREVADH™ Mesh is comprised of biocompatible materials that are in compliance with ISO 10993-1 and/or USP standards.

PERFORMANCE DATA:

Bench and animal testing has been conducted to evaluate the performance characteristics of PREVADH™ Mesh. Results of mechanical properties testing show that PREVADH™ Mesh has similar performance characteristics to the predicate VICRYL Mesh.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2008

Sofradim Production
% Covidien
Ms. Sharon Alexander
Senior Associate, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K073287
Trade/Device Name: PREVADH™ Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: February 15, 2008
Received: February 19, 2008

Dear Ms. Alexander:

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073287

Indications For Use

510(k) Number (if known): K073287

Device Name: PREVADH™ Mesh

Indications For Use:

PREVADH™ mesh is indicated for use when a temporary wound support is required in abdominopelvic surgery. The resorbable hydrophilic film minimizes tissue attachment to the mesh in the case of direct contact with the viscera.

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)

for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073287