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JAN 14 2010

ADMINISTRATIVE INFORMATION

Manufacturer Name: Promethean Surgical Devices
111 Roberts Street, Suite G2,
East Hartford, CT 06108

Official Contact: Kenneth K. Kleinhenz
Regulatory Affairs
Telephone (858) 458-0900
Fax (858) 458-0994

DEVICE NAME

Classification Name: Surgical Mesh, Polymeric

Trade/Proprietary Name: HydroCoat Mesh

ESTABLISHMENT REGISTRATION NUMBER

This is our first device applications to FDA. We will register and pay the fee within 30 days of FDA's approval/clearance of this device.

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 878.3300, Surgical Mesh are polymeric screens intended to be implanted to reinforce soft tissues. These devices are classified as Class II. Surgical Mesh have been assigned Product Code FTL.

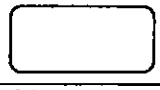
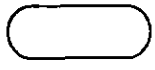
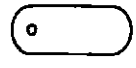
INTENDED USE

The HydroCoat Mesh is indicated for use in general surgical procedures for reinforcement of soft tissue where weakness exists. The HydroCoat Mesh may be used for the repair of abdominal wall hernia, including inguinal, femoral, and incisional hernia, uterovaginal prolapse, and other fascial deficiencies that require support material.

DEVICE DESCRIPTION

The HydroCoat Mesh is a polypropylene surgical mesh coated with polyurethane and intended for trauma and reconstructive surgical procedures involving soft tissues. The HydroCoat Mesh is fabricated from a knitted monofilament, medical-grade polypropylene fiber that links each porous window of the mesh, allowing for elasticity in both directions. The HydroCoat Mesh is available in various shapes and sizes for use in reinforcing soft tissues where weakness exists. The HydroCoat Mesh can be cut to most any shape or size for specific soft tissue reinforcement needs.

The Promethean Surgical Devices HydroCoat Mesh is provided in various shapes such as rectangles, ovals, ellipticals and circles and will be provided in other shapes and sizes as needed for particular soft tissue reinforcement applications. The Promethean Surgical Devices HydroCoat Mesh is provided in sheets of various shapes and sizes as outlined in the table below:

Rectangular 	Square 	Elliptical 	Oval 	Round 	Keyhole 
12" x 12"	12" x 12"	12" x 10"	12" x 9"	8" diameter	1.5" x 8"
12" x 10"	10" x 10"	10" x 8"	10" x 7"	6" diameter	3" x 7"
10" x 8"	8" x 8"	8" x 6"	8" x 5"	5" diameter	
8" x 6"	6" x 6 "	7" x 5 "	7" x 4"	4" diameter	
7" x 5"	4" x 4"	6" x 4 "	6" x 3"	3" diameter	
6" x 4"		5" x 3"	5" x 2"		
5" x 3"		4" x 2"	4" x 1"		
4" x 2"					

The thickness of the Promethean Surgical Devices HydroCoat Mesh ranges from 0.015" to 0.030" (0.38mm to 0.76mm) according to the region to be treated. The Promethean Surgical Devices HydroCoat Mesh is provided in flat sheets that contain micropores that range in size from $3mm^2$ to $5mm^2$. The HydroCoat Mesh has an overall areal density of 1.1001 oz/yd^2 (37.3 g/m^2).

Material Composition

The Promethean Surgical Devices HydroCoat Mesh is fabricated from a polypropylene yarn that is coated with a polyether urethane urea.

In Vitro Testing

Mechanical testing was performed on the Promethean Surgical Devices HydroCoat Mesh which determined the HydroCoat Mesh to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

EQUIVALENCE TO MARKETED PRODUCT

The Promethean Surgical Devices HydroCoat Mesh shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: Mentor Suspend Sling (K980483), Artimplant AB SportMesh / Artelon Tissue Reinforcement (K071887), Artimplant AB SportMesh (K052830), the Mpathy Medical Minimesh (K041632), and the Ethicon Mersilene Mesh (pre-amendment); Class II medical devices that were cleared for marketing in the United States under K980483, K071887, K052830, K041632, and pre-amendment respectively.

Indications for Use

The HydroCoat Mesh and the predicate devices are substantially equivalent with respect to their indications for use as they are all indicated for the same general surgery procedures requiring the reinforcement of soft tissues in the same peritoneal anatomy.

Design and Materials

The design of the Promethean Surgical Devices HydroCoat Mesh and the Mentor Suspend Sling (K980483), Artimplant AB SportMesh / Artelon Tissue Reinforcement (K071887), Artimplant AB SportMesh (K052830), the Mpathy Medical Minimesh (K041632), and the Ethicon Mersilene Mesh predicate devices are substantially equivalent as they are all thin, flat sheets of various shapes and sizes that can be cut to shape with surgical scissors and are all fabricated from a polymeric fiber that is knitted into a pattern that creates a meshed network of yarn with a uniform pattern of holes. The Promethean Surgical Devices HydroCoat Mesh, the Mpathy Medical Minimesh (K041632), and the Ethicon Mersilene Mesh devices are substantially equivalent as they share a common design feature of being fabricated from a polypropylene fiber. The Promethean Surgical Devices HydroCoat Mesh and the Mentor Suspend Sling (K980483), Artimplant AB SportMesh / Artelon Tissue Reinforcement (K071887), and Artimplant AB SportMesh (K052830) predicate devices are substantially equivalent as they all share the design feature of utilizing a polyurethane urea materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Promethean Surgical Devices, Inc.
% Mr. Kenneth K. Kleinhenz
Regulatory Affairs
111 Roberts Street, Suite G2
East Hartford, Connecticut 06108

JAN 1 4 2010

Re: K090271
Trade/Device Name: HydroCoat Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: January 05, 2010
Received: January 06, 2010

Dear Mr. Kleinhenz:

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 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

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Indications for Use

Re: K090271

Device Name: HydroCoat Mesh

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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)

David Krause

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

510(k) Number K090271