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JUN 19 2008

New 510 (k) Notification for Herniamesh Relimesh

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Submitter: Herniamesh SRL
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Contact: Lorena Trabucco
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Tel 516 987-9364 Fax 516 938-2751

Device Name: Relimesh

Predicate Devices: **K971745** Composite Mesh (C.R. Bard Inc.)
K070625 Hermesh 7 (Herniamesh Srl)

Device Description: Relimesh prostheses are dual component meshes made of non-absorbable monofilament polypropylene mesh on one side and a layer of ePTFE on the other side.

Relimesh is warp knitted in such a way that the mesh may be cut into preshaped designs without unraveling and will maintain excellent isotropic properties because of its knitted construction. The ePTFE layer is heat sealed to the polypropylene layer

These meshes have the necessary strength, flexibility, and durability for the various stresses which may be encountered in the body.

The devices are supplied as sterile, single-use surgical meshes.

Intended Use: Relimesh prostheses are intended for use in the reconstruction of soft tissue deficiencies, such as but not limited to the repair of hernias and chest wall defects

Relimesh is a prescriptive device and should only be used by a licensed physician.

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Testing:

The patient contact materials used in these devices are the same as predicate devices. All are made of 100% Polypropylene with and without ePTFE. They have similar technological characteristics.

Polypropylene and ePTFE have a long history of biocompatibility.

Relimesh prostheses comply with the requirements of ISO 10993 Biological Evaluation of Medical Devices, In addition appropriate tests have been conducted in accordance with the FDA Guidance Document "Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh"

The following tests were performed to show the safety, efficacy and performance of the product. Mutagenicity, Cytotoxicity, Hemolysis, Allergic Sensitization, Systemic Toxicity, Ethylene Oxide Residual <1ppm, Sterility Assurance level 10^{-6}, and Ethylene Chlorohydrin Level <2ppm. Please refer specific tests for more details.

Summary of Similarities & Differences:

Relimesh and the predicate devices have the same intended use, which is for the reconstruction of soft tissue deficiencies. The technological characteristics are the same or similar to the predicate devices in that the materials used to manufacture theses products are similar; polypropylene and ePTFE. The differences to predicate devices include mesh thickness, the shape, mesh knit structure, diameter of the filament used to weave the mesh and the thickness of the ePTFE layer. Please refer to charts on following page for specific details.

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Technological Characteristics Comparison Table

Product	Mesh Weight g / sq. m	Filament Diameter µ	Thickness Mesh mm	Material	% Porosity	Sizes Cm
Relimesh Herniamesh SRL	78 ± 6%	120	0.5 ± 10%	Polypropylene & ePTFE	86.8	flat sheets of various sizes & preshapes
Hermesh 7 Herniamesh SRL (K070625)	19	80	0.27 mm	100 % Polypropylene	91.9	flat sheets of various sizes & preshapes
Composite Mesh C.R. Bard Inc. (K 971745)	214	160	1.5 mm	Polypropylene & ePTFE	83	flat sheets of various sizes & preshapes

Product	Suture Retention N	Burst strength Kpa	Tensile strength N/cm
Relimesh Herniamesh SRL	24.60	378	24 ± 6
Hermesh 7 Herniamesh SRL (K070625)	8.75	359	17.7
Composite Mesh C.R. Bard Inc. (K 971745)	26 ± 7.56	1316 ± 3.8	N/A

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Table of Similarities and Differences / Substantial Equivalence to Predicate Devices

Feature	**Herniamesh Relimesh**	**Bard Composix EX Mesh**	**Herniamesh Hermesh 7**
510(k) No.	**To be determined**	**K971745**	**K070625**
Classification	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh
Indication	mesh used for the reconstruction of soft tissue deficiencies	mesh used for the reconstruction of soft tissue deficiencies	mesh used for the reconstruction of soft tissue deficiencies
Product Design	monofilament polypropylene / ePTFE	monofilament polypropylene / ePTFE	Polypropylene
Materials	Polypropylene / ePTFE	Polypropylene / ePTFE	Polypropylene
Sterilization	EtO	EtO	EtO
Packaging	Double tyvek pouch	Double tyvek pouch	Double tyvek pouch
Tissue In growth	Complete tissue incorporation of implant, ePTFE side reduces incidence of	Complete tissue incorporation of implant, ePTFE side reduces incidence of	Complete tissue incorporation of implant

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2008

Herniamesh S.R.L.
% Marketing Solutions Inc.
Ms. Lorena Trabucco
8 Orange Drive
Jericho, New York 11753

Re: K081327
Trade/Device Name: Relimesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 3, 2008
Received: June 5, 2008

Dear Ms. Trabucco:

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

Indications for Use

510(k) Number (if known): K081327

Device Name: Relimesh

Indications For Use:

Relimesh prostheses are intended for use in the reconstruction of soft tissue deficiencies such as but not limited to hernia repairs and chest wall defects.

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)

Neil R Ogden for mkn

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

510(k) Number K081327