K070625 Page 1/2

August 1, 2007

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Submitter: Herniamesh SRL
Via Fratelli Meliga 1/C
Chivasso, Italy
Tel +39 011 9196236 Fax +39 011 9196239

Contact: Lorena Trabucco
540 MUTTONTOWN EASTWOODS ROAD
Syosset, NY 11791
Tel 516 987-9364 – 516 584 6818
e-mail: lorenat63@aol.com

Date Prepared: April 16, 2012 (Revised)

Classification: Polymeric Surgical Mesh (product code FTL) Class II device per 21 CFR 87.8.330

Common Name: Polymeric Surgical Mesh

Proprietary Name: Hermesh 7

Predicate Devices:
K053424 POPMESH (Caldera Medical Inc.)
K041632 MINIMESH® (Mpathy Medical Devices LTD.)
K973955 Herniamesh surgical meshes (Herniamesh Srl)
K043259 BioBlanket (Kensey Nash)

Device Description: Hermesh 7 prosthesis are non- absorbable monofilament polypropylene meshes constructed from knitted monofilaments of extruded polypropylene.

They are warp knitted in such a way that the mesh may be cut into preshaped designs without unraveling. They maintain excellent isotropic properties because of its knitted construction.

Hermesh 7 polypropylene 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: May be used for the repair of abdominal wall hernia, including inguinal, femoral, and incisional in open or laparoscopic abdominal procedures.

Hermesh 7 are prescriptive devices and should only be used by a licensed physician.

Hermesh 7 have the same indications as predicate devices.

Testing:

The patient contact materials used in these devices are the same as predicate devices. All are made of 100% Polypropylene and have similar technological characteristics. Please see Material Safety Data Sheet on page 85 and technological characteristics Comparison table on page 8.

Polypropylene has a long history of biocompatibility.

Hermesh 7 polypropylene meshes 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 Herniamesh T-Sling. Mutagenicity, Cytotoxicity, Hemolysis, Allergic Sensitization, Systemic Toxicity, Ethylene Oxide Residual <1ppm, Sterility Assurance level 10^{-6} , and Ethylene Chlorohydrin Level <2ppm. Please refer to pages 11 and 14-80 for details of tests.

HERNIAMESH SRL
Sede legale Via Fratelli Melga 1/C – 10034 Chivasso (TO)
Cap. Soc. € 98.800 i.v. – P.I. 02791540616 – C. F. 02245180613 - N. Iscrizione Rea Torino TO-960622
Tel. +39-0119196236 – fax +39-0119196239

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Marketing Solutions, Incorporated/Herniamesh SRL
% Ms. Lorena Trabucco
540 Muttontown Eastwoods Road
Syosset, New York 11791

JUL 12 2012

Re: K070625
Trade/Device Name: Hermesh 7
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: July 25, 2007
Received: July 27, 2007

Dear Ms. Trabucco:

This letter corrects our substantially equivalent letter of August 1, 2007.

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 (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,

Mark Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known) K070625

Device Name: Hermesh 7

Indications For Use:

Hermesh 7 monofilament polypropylene mesh may be used for repair of abdominal wall hernia, including inguinal, femoral, and incisional, in open or laparoscopic abdominal procedures.

Prescription Use__x OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

David Krause for MM

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

510(k) Number K070625

HERNIAMESH SRL
Sede legale Via Fratelli Meliga 1/C – 10034 Chivasso (TO)
Cap. Soc. € 98.800 i.v. – P.I. 02791540616 - C. F. 02245180613 - N. iscrizione Rea Torino TO-960622
Tel. +39-0119196236 – fax +39-0119196239
Mail: info@herniamesh.it - Mail certificata: amministrazione@pec.herniamesh.it - Sito internet www.herniamesh.com