K973955

PREMARKET NOTIFICATION FOR HERNIAMESH PRODUCTS

MAY 1 1 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

The Herniamesh surgical meshes are substantially equivalent to Trelex mesh currently marketed by Meadox Medicals, and to Marlex Mesh and the Marlex Mesh Dart currently marketed by Bard Vascular Systems Division, C.R. Bard, Inc. Trelex Mesh and Marlex mesh are both available in a variety of shapes and sizes.
The "510 (k) "substantial Equivalence" Decision-Making Process (Detailed)" decision tree was utilized to make a determination of substantial equivalence (see Exhibit 1). The answers to the following four questions lead to a determination of substantial equivalence.

1. **Does New Device Have Same Indication Statement?**

   Yes, all of the indications for Herniamesh products are identical to those of the predicate devices. All are indicated for the repair of abdominal wall hernias, femoral hernias or chest wall defects.

2. **New Device Has Same Intended Use and May be "Substantially Equivalent"?**

   Yes, the intended use of Herniamesh products are the same as predicate devices.
   Herniamesh products Hertra 1. 2 & 2A and Hermesh 3, 4 & 5 have the same intended uses as Trelex Mesh and Marlex Mesh. All are used in the repair of primary or recurrent inguinal hernias (particularly when facial structures are weak), primary or recurrent inscisional hernias, hernias so large that the fascial edges of the hernial ring cannot be approximated (generally one-fourth of the abdominal wall), femoral hernias, or chest wall defects where it is not possible to use autogenous tissue to prevent or correct lung herniation.
   Herniamesh Plugs T1, T2 & T3 have the same intended use as the Marlex Mesh Dart which is used for the repair of hernias with a three dimensional shape i.e. femoral, crural, inguinocrueal or large recurrent inguinal hernias.

3. **Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?**

   Yes, Herniamesh products have the same technological characteristics as predicate devices.
   Herniamesh products, Trelex mesh, Marlex Mesh and the Marlex Mesh Dart are all made of the same material. All are a polypropylene monofilament of various thickness.
   The design and structureof Herniamesh products Hertra 1, 2, & 2A, Hermesh 3, 4 & 5 and Plug T1 are the same as Trelex Mesh and Marlex Mesh. All are a monofilament knitted into a mesh design and flat in structure.
   The design and srtucture of Herniamesh Plugs T2 and T3 are the same as the Marlex Mesh Dart. All are a monofilament knitted into a mesh design and three-dimensional in structure with the same indications for use.The major differences between all of these products are the thickness of the monofilament and the type of knit used to achieve the mesh design.

4. **Are The Descriptive Characteristics Precise Enough to Ensure Equivalence?**

   Yes, since Herniamesh products are constructed of the same materials, have the same design and the same structure as predicate devices then the descriptive characteristics that apply to Trelex Mesh, Marlex Mesh and the Marlex Mesh Dart also apply to Herniamesh products. The process validation will demonstrate that these properties are maintained.

"Substantially Equivalent" Determination

Based on the above answers the surgical meshes produced by Herniamesh are substantially equivalent to the predicate devices, Trelex Mesh, Marlex Mesh and the Marlex Mesh Dart.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1 1998

Ms. Lorena A. Trabucco
Herniamesh
1802 North 103 Avenue
Omaha, Nebraska 68114

Re: K973955
Trade Name: Herniamesh Surgical Meshes
Regulatory Class: II
Product Code: FTL
Dated: March 9, 1998
Received: March 12, 1998

Dear Ms. Trabucco:

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

K973955

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510(k) Number (if known): K973955

Device Name: HERNIAMESH - SURGICAL MESHES

Indications For Use:

All meshes made by Herniamesh are made of monofilament polypropylene. The meshes are non biodegradable and highly permeable. The meshes are designed to be used in the surgical repair of abdominal wall hernias such as primary or recurrent inguinal hernias, femoral hernias, inscisional hernias as well as thoracic wall defects.
Each of the Herniamesh products were designed with specific characteristics for each of the different types of hernioplasty. (please refer to product pamphlet)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973955

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

(Optional Format 1-2-96)