K063739

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PART 2

1 510(K) SUMMARY AS REQUIRED BY 21 CFR 807.92

Per Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Genzyme Corporation is providing a summary of the safety and effectiveness information available for Sepramesh™ IP Bioresorbable Coating – Permanent Mesh (Sepramesh™ IP).

1.1 Sponsor/Applicant Name and Address:

Genzyme Corporation

500 Kendall Street

Cambridge, MA 02142

1.2 Sponsor Contact Information:

Matthew Hibbert

Senior Associate, Regulatory Affairs

T: (617) 374-7463

F: (617) 761-8414

matthew.hibbert@genzyme.com

1.3 Date of Preparation of 510(k) Summary:

December 15, 2006

1.4 Device Trade or Proprietary Name:

Sepramesh™ IP Bioresorbable Coating/Permanent Mesh

1.5 Device Common/Usual or Classification Name:

Surgical Mesh (21 CFR 878.3300, Product Code FTL)

1.6 Identification of the Legally Marketed Devices to which Equivalence is Being Claimed:

Name of Predicate Device	Name of Manufacturer (Town, State)	510(k) Number
Sepramesh™ IP	Genzyme Corporation, Cambridge, MA	K053066

1.7 Device Description:

Sepramesh™ IP Bioresorbable Coating/Permanent Mesh (Sepramesh™ IP) is a dual-component (absorbable and non-absorbable), sterile prosthesis designed for the reconstruction of soft tissue deficiencies. Sepramesh™ IP is co-knitted using polypropylene and polyglycolic acid (PGA) fibers to result in a two-sided mesh with a polypropylene surface and PGA surface. Genzyme will offer two versions of the device. The first version utilizes violet dyed PGA fibers. The second version utilizes natural beige PGA fibers instead of the original violet version. The mesh is coated on the PGA surface with a bioresorbable coating of chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC) and a polyethylene glycol (PEG) based hydrogel.

The uncoated side of the mesh allows a prompt fibroblastic response through the interstices of the mesh, encouraging tissue ingrowth, similar to polypropylene mesh alone. The coated side of the mesh provides a hydrophilic bioresorbable layer, separating the mesh from underlying tissue and organ surfaces during the critical wound-healing period resulting in minimal tissue attachment and visceral adhesions to the mesh. Shortly after placement, the biopolymer coating becomes a hydrated gel that is resorbed from the site in less than 30 days. The absorption of the PGA fibers is essentially complete between 50 and 80 days. The polypropylene mesh is permanent and allows for tissue ingrowth.

1.8 Intended Use:

Sepramesh™ IP Bioresorbable Coating/Permanent Mesh is indicated for use in the reconstruction of soft tissue deficiencies such as for the repair of hernias.

1.9 Comparison of Technological Characteristics of Sepramesh™ IP with Legally Marketed Devices:

Table 5 is the Table of Similarities and Differences between Genzyme's Sepramesh™ IP Bioresorbable Coating/Permanent Mesh and the legally marketed devices identified in **Section 1.6**.

Table 5: Table of Similarities and Differences/Substantial Equivalence to Predicate Devices

Feature	**Sepramesh™ IP Bioresorbable Coating/Permanent Mesh**	**Proposed Sepramesh™ IP Bioresorbable Coating/Permanent Mesh**
Classification	Class II: Polymeric Surgical Mesh	Same
Indication	Reconstruction of soft tissue deficiencies, such as for the repair of hernias	Same
Labeling Claims	Biopolymer surface minimizes tissue and visceral adhesions to device	Same
Product Design	Polypropylene/PGA mesh with biopolymer coating on one surface	Same
Materials	Polypropylene, PGA (violet dyed fibers or natural beige fibers), HA/CMC, PEG based hydrogel	Same
Sizes	3"x6" to 8"x12"	Add 12"x14"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2007

Genzyme Biosurgery
% Mr. Matthew Hibbert
Senior Associate, Regulatory Affairs
55 Cambridge Parkway
Cambridge, Massachusetts 02142

Re: K063739
Trade/Device Name: Sepramesh™ IP Bioresorbable Coating – Permanent Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: December 15, 2006
Received: December 18, 2006

Dear Mr. Hibbert:

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.

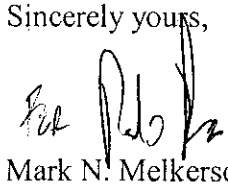
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 Form

510(k) Number (if known): To be determined K063739

Device Name: Sepramesh™ IP Bioresorbable Coating – Permanent Mesh

Indications for Use:

Sepramesh™ IP Bioresorbable Coating – Permanent Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.

Presciption Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(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, and Neurological Devices

510(k) Number K063739