

DEC 19 2005

genzyme

Sepramesh™ IP Bioresorbable Coating/Permanent Mesh

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 Barrier – Permanent Mesh (Sepramesh™ IP), as well as the substantial equivalence decision making process used for Sepramesh™.

1.1 Sponsor/Applicant Name and Address:

Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142

1.2 Sponsor Contact Information:

Lisa D. Crockett
Sr. Regulatory Affairs Associate
Phone: 617.591.5548
FAX: 617.761.8414
email: lisa.crockett@genzyme.com

1.3 Date of Preparation of 510(k) Summary:

October 27, 2005 October 26, 2005

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 FTM)

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	K040868
Sepramesh™	Genzyme Corporation,	K994328

Proprietary and Confidential

DOCUMENT INFO: SEPRAMESH_IP_510K_FINAL.WO APPENDICES1.DOC

	Cambridge, MA	
Bard® Composix® E/X Mesh	Davol Inc., Cranston, RI	K002684
Bard® Mesh	Davol Inc., Cranston, RI	Pre-Amendment
Vicryl™ Knitted Mesh	Ethicon Inc., Somerville, NJ	K810428
Dexon® PGA Mesh	Davis & Geck Inc., Norwalk, CT	K830889

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, previously cleared through K040868 utilizes violet dyed PGA fibers. The second version described in this submission utilizes natural beige PGA fibers. The mesh is coated on the PGA surface with a bioresorbable barrier 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 16 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 16: Table of Similarities and Differences/Substantial Equivalence to Predicate Devices

Feature	Proposed Sepramesh™ IP Bioresorbable Coating/Permanent Mesh	Sepramesh™ IP Bioresorbable Coating/Permanent Mesh	Sepramesh™ Biosurgical Composite	Bard® Composix® E/X Mesh	Bard® Mesh	Dexon® PGA Mesh	Comments on Differences
510(k) No.	To be determined	K040868	K994328	K002684	Pre-Amendment	K830889	Not Applicable
Classification	Class II: Polymeric	Class II: Polymeric	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh	Substantially Equivalent
Indication	Reconstruction of soft tissue deficiencies, such as for the repair of hernias	Reconstruction of soft tissue deficiencies, such as for the repair of hernias	Reconstruction of soft tissue deficiencies, such as for the repair of hernias	Reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects	Reinforce soft tissue where weakness exists, i.e., repair of hernias and chest wall defects	External organ support and organ architecture preservation	Substantially Equivalent
Labeling Claims	Biopolymer surface minimizes tissue and visceral adhesions to device	Biopolymer surface minimizes tissue and visceral adhesions to device	HA/CMC surface minimizes tissue and visceral adhesions to device	ePTE minimizes adhesions to device	None	None	Substantially Equivalent
Product Design	Polypropylene/PGA mesh with biopolymer coating on one surface	Polypropylene/PGA mesh with biopolymer coating on one surface	Polypropylene mesh with HA/CMC coating on one surface	Polypropylene mesh with an ePTE layer stitched on one surface	Polypropylene mesh	PGA Mesh	Coated surface placed facing viscera.

1.10 Summary of Nonclinical Data:

The biocompatibility and safety tests conducted for Sepramesh™ IP were selected in accordance with the Blue Book Memorandum G95-1, "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. Based on the results from these studies, Sepramesh™ IP is considered to be non-toxic, non-mutagenic, non-sensitizing, biocompatible and safe.

The effectiveness of Sepramesh™ IP was compared *in vivo* in a rabbit hernia repair model to Bard® Composix® E/X Mesh and Bard® Mesh. The overall performance of Sepramesh™ IP, including adhesion formation and tissue ingrowth, was substantially equivalent to these hernia repair products. Cellular response and tissue ingrowth for all three groups was comparable. Sepramesh™ IP performed substantially equivalent or better than Bard® Composix® E/X Mesh and Bard® Mesh in all of the evaluated adhesion reduction categories.

The physical and mechanical characteristics of Sepramesh™ IP, such as mesh thickness, mesh knit characteristics, pore size, mesh mass/area, suture retention strength, tear propagation strength and burst strength, are substantially equivalent to the currently marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2005

Ms. Lisa D. Crockett
Sr. Regulatory Affairs Associate
Genzyme Corporation
55 Cambridge Parkway
Cambridge, Massachusetts 02142

Re: K053066

Trade/Device Name: Sparamesh IP Bioresorbable Coating/Permanent Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: October 31, 2005
Received: December 1, 2005

Dear Ms. Crockett:

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.

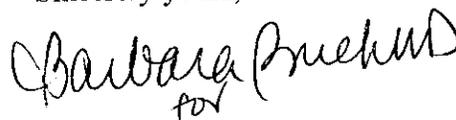
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443 6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Mark N. Melkerson" with a small "for" written below the name.

Mark N. Melkerson
Acting 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): K053066

Device Name: Sepramesh™ IP Bioresorbable Barrier - Permanent Mesh

Indications For Use:

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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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510(k) Number K053066