JUN - 4 2004

K040868

1/3

10.0 510(K) SUMMARY (as required by 21 CFR 807.92)

Pursuant to 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), as well as the substantial equivalence decision making process used for Sepramesh™.

10.1 Sponsor/Applicant Name and Address:

Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142

10.2 Sponsor Contact Information:

Michael G. Halpin
Director, Regulatory Affairs
Phone: 617.591.5836
FAX: 617.761.8414
email: michael.halpin@genzyme.com

10.3 Date of Preparation of 510(k) Summary:

May 25, 2004

10.4 Device Trade or Proprietary Name:

Sepramesh™ IP Bioresorbable Coating – Permanent Mesh

10.5 Device Common/Usual or Classification Name:

Surgical Mesh

K040868

2/3

10.6 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™	Genzyme Corporation, Cambridge, MA	K994328
Bard® Mesh	Davol Inc., Cranston, RI	Pre-amendment
Bard® Composix® E/X Mesh	Davol Inc., Cranston, RI	KK002684
Vicryl™ Knitted Mesh	Ethicon Inc., Somerville, NJ	K810428
Dexon® PGA Mesh	Davis & Geck Inc., Norwalk, CT	K830889

10.7 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. The mesh is coated on the PGA surface with a bioresorbable, chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC) and a polyethylene glycol (PEG) based hydrogel.

The fascial side of the mesh allows a prompt fibroblastic response through the interstices of the mesh, encouraging tissue ingrowth, similar to polypropylene mesh alone. The visceral 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.

10.8 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.

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

Table 15 is the Table of Similarities and Differences between Genzyme's Sepramesh™ IP Bioresorbable Coating – Permanent Mesh and the legally marketed devices identified in **Section 10.6.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2004

Mr. Michael G. Halpin
Director, Regulatory Affairs
Genzyme Corporation
500 Kendall Street
Cambridge, Massachusetts 02142

Re: K040868
Trade/Device Name: Sepramesh™ IP Bioresorbable Coating – Permanent mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: April 1, 2004
Received: April 5, 2004

Dear Mr. Halpin:

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.

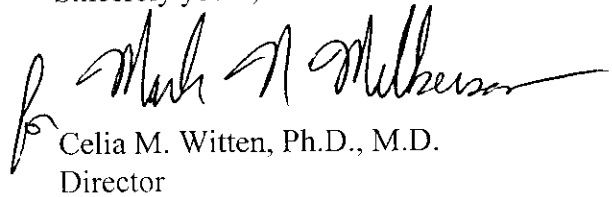
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K040868

Indications for Use Form

510(k) Number (if known): K040868

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.

Prescription 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)

for Mark N Milhous

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

510(k) Number K040868