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™ Biosurgical Composite (Sepramesh™), as well as the substantial equivalence decision making process used for Sepramesh™.

10.1 Sponsor/Applicant Name and Address:

Genzyme Corporation
One Kendall Square
Cambridge, MA 02139

10.2 Sponsor Contact Information:

John A. DeLucia
Director, Regulatory Affairs
Phone: 617/374-7266
FAX: 617/374-7470
email: john.delucia@genzyme.com

10.3 Date of Preparation of 510(k) Summary:

December 21, 1999

10.4 Device Trade or Proprietary Name:

Sepramesh™ Biosurgical Composite

10.5 Device Common/Usual or Classification Name:

Surgical Mesh

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
Bard® Mesh	Davol Inc., Cranston, RI	Pre-amendment
Bard® Composix™ Mesh	Davol Inc., Cranston, RI	K971745
Mersilene™ Mesh	Ethicon, Inc., Somerville, NJ	Pre-amendment

10.7 Device Description:

Sepramesh™ Biosurgical Composite (Sepramesh™) is a dual-component (absorbable and non-absorbable), sterile prosthesis designed for the reconstruction of soft tissue deficiencies. Sepramesh™ is constructed of a polypropylene mesh that is coated on one side with a bioresorbable coating composed of sodium hyaluronate (HA) and carboxymethylcellulose (CMC).

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 and providing support for soft tissue repair. The HA/CMC side of the mesh provides a hydrophilic bioresorbable coating separating the mesh from underlying tissue and organ surfaces during the critical wound-healing period to minimize tissue attachment to the mesh. Shortly after placement, the HA/CMC coating becomes a hydrated gel that is slowly resorbed from the site of placement within 5-7 days and excreted from the body within 30 days.

10.8 Intended Use:

Sepramesh™ Biosurgical Composite 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™ with Legally Marketed Devices:

Table 12 is the Table of Similarities and Differences between Genzyme's Sepramesh™ Biosurgical Composite and the legally marketed devices identified in **Section 10.6**.

Table 12: Table of Similarities and Differences/Substantial Equivalence to Predicate Devices

Feature	Sepramesh™ Biosurgical Composite	Bard® Mesh	Mersilene™ Mesh	Bard® Composix™ Mesh	Comments on Differences
510(k) No.	To be determined	Pre-amendment	Pre-amendment	K971745	Not Applicable
Classification	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	Reinforce soft tissue where weakness exists, i.e., repair of hernias and chest wall defects	Repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material	Reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects	Substantially Equivalent
Labeling Claims	HA/CMC surface minimizes tissue and visceral adhesions to device	None	None	ePTFE minimizes adhesions to device	Substantially Equivalent
Product Design	Polypropylene mesh with HA/CMC coating on one surface	Polypropylene mesh	Polyester mesh	Two layers of polypropylene mesh with PTFE coating on one surface	HA/CMC and ePTFE surface placed facing viscera.
• Materials	Polypropylene, HA/CMC, PLA/PGA	Polypropylene	Polyethylene terephthalate (PET)	Polypropylene, ePTFE	PLA/PGA bonds HA/CMC coating to polypropylene.
Coating	Yes (HA/CMC)	No	No	Yes (ePTFE)	Substantially Equivalent

Table 12: Table of Similarities and Differences/Substantial Equivalence to Predicate Devices (continued)

Feature	Sepramesh™ Biosurgical Composite	Bard® Mesh	Mersilene™ Mesh	Bard® Composix™ Mesh	Comments on Differences
Mesh Design	Single bar knit from 6 mil monofilament polypropylene fiber	Single bar knit from 6 mil monofilament polypropylene fiber	Two bar knit from multifilament PET fiber	Indeterminate	Substantially Equivalent
• Mesh Pore Size	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Performance Results					
• Burst Strength	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent	Not tested	Substantially Equivalent
• Suture Retention	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent	Not tested	Substantially Equivalent
• Tissue Ingrowth	Complete tissue incorporation of implant	Complete tissue incorporation of implant	Not tested	Complete tissue incorporation of implant	Substantially Equivalent
• Tissue Attachment (Adhesions) to Mesh	Decreased compared to Bard® Mesh and Composix™	Extensive adhesions	Not tested	Decreased adhesions compared to Bard® Mesh	Substantially Equivalent
Sterilization	Gamma	EtO	Gamma, EtO, or Steam	EtO	Substantially Equivalent
Sizes	3"x6" to 8"x12"	1"x4" to 10"x14"	2.5"x4.5" and 12"x12"	2"x4" to 8"x10"	Substantially Equivalent

10.10 Summary of Nonclinical Data:

The biocompatibility and safety tests conducted for Sepramesh™ 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™ is considered to be non-toxic, non-mutagenic, non-sensitizing, biocompatible and safe.

The effectiveness of Sepramesh™ was compared *in vivo* in a rabbit hernia repair model to Bard® Mesh and Bard® Composix™ Mesh. The overall performance of Sepramesh™, 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™ performed substantially equivalent or better than Bard® Mesh and Bard® Composix™ Mesh in all of the evaluated adhesion reduction categories.

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

10.11 Substantial Equivalence Decision Making Process:

The guidance document titled, "Premarket Notification 510(k): Regulatory Requirements for Medical Devices," Appendix A3, "Substantial Equivalence" Decision-Making Process (Detailed)" revised August 1992 by Center for Devices and Radiological Health, was used to determine the substantial equivalence for Genzyme's Sepramesh™. Please refer to **Appendix 1** for a diagram of the 510(k) Decision Tree. The answers to the questions listed below lead to a determination of substantial equivalence to the predicate devices.

a. Does the new device have the same indication statement?

Yes. Sepramesh™ has the same intended use as Bard® Mesh (pre-amendment device), Bard® Composix™ Mesh (K971745) and Mersilene™ Mesh (pre-amendment device) which are legally marketed hernia repair devices. Sepramesh™ Biosurgical Composite is indicated for use in the reconstruction of soft tissue deficiencies such as for the repair of hernias. Therefore, Sepramesh™ has the same intended use as the predicate devices and is considered to be "substantially equivalent."

b. Does the new device have the same technological characteristics, e.g. design, materials etc?

No. Sepramesh™ has different technological characteristics. However, the technological differences meet or exceed the functional requirements of surgical meshes compared to the predicate devices. Please refer to **Table 12** for the Table of Similarities and Differences/Substantial Equivalence to predicate devices.

c. Could the new technological characteristics affect safety and effectiveness?

Yes, the new technological characteristics could affect safety and effectiveness. However, the differences in safety and effectiveness meet or exceed the requirements of surgical meshes compared to the predicate devices.

d. Do the new characteristics raise new types of safety or effectiveness questions?

No. The safety and effectiveness questions are not new and include issues such as materials, pore size, mesh strength, suture retention, biocompatibility and tissue ingrowth. Sufficient data has been provided in this premarket notification to address any new safety and efficacy questions. Additionally, there are a variety of other meshes currently on the market with different characteristics compared to Sepramesh™ or the predicate devices.

e. Do accepted scientific methods exist for assessing the effects of the new characteristics?

Yes. The effects of the new characteristics of Sepramesh™ can be assessed by common methods utilized for surgical meshes. These include mechanical testing, scanning electron microscopy, biocompatibility testing and *in vivo* safety and effectiveness testing.

f. Are performance data available to assess the effects of the new characteristics?

Yes. Extensive testing has been performed to assess the effects of the new characteristics of Sepramesh™. These tests compared the effects of Sepramesh™ against the predicate devices as applicable, and included mechanical testing, scanning electron microscopy, biocompatibility testing and *in vivo* safety and effectiveness testing.

g. Do performance data demonstrate equivalence?

Yes. Based on the results of the tests summarized in **Section 8** of this application, the physical and mechanical characteristics of Sepramesh™ are comparable to the currently marketed predicate devices. The results of the *in vivo* testing indicate that tissue ingrowth is comparable to that of the predicate devices and that the tissue attachment at the visceral surfaces in contact with Sepramesh™ is minimized compared to the predicate devices. Results from all the safety tests conducted demonstrate that Sepramesh™ is non-toxic, non-mutagenic and biocompatible.

Based on this information, Sepramesh™ is determined to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2000

Mr. John A. DeLucia
Director, Regulatory Affairs
Genzyme Corporation
One Kendall Square
Cambridge, Massachusetts 02139-1562

Re: K994328
Trade Name: Sepramesh™ Biosurgical Composite
Regulatory Class: II
Product Code: FTL
Dated: December 21, 1999
Received: December 22, 1999

Dear Mr. DeLucia:

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,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K994328

INDICATIONS FOR USE FORM

(per Attachment #1 of CDRH's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh"" March 2, 1999)

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

Device Name: Sepramesh™ Biosurgical Composite

Indications for Use:

Sepramesh™ Biosurgical Composite is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.

DRD for 320

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994328

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____

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