JUN 2 2 1999

K991191

EXHIBIT I

510(k) Summary of Substantial Equivalence

BONDEK® Synthetic Absorbable Surgical Suture

In accordance with the requirements of 21 CFR § 807, this summary is formatted with the Agency's final rule "....510(k) Summaries and 510(k) Statements..." and can be used to provide equivalence summary to anyone requesting it from the Agency.

Manufacturer

Genzyme Surgical Products
600 Airport Road
Fall River, MA 02720-4740

Contact Person

Mary E. Gray
Phone: (508) 677-6512
Fax: (508) 677-6663
e-mail: mgray@genzyme.com

Device Information

Trade Name:	Bondek® Polyglycolic Acid Synthetic Absorbable Surgical Suture
Common Name:	Polyglycolic Acid Synthetic Absorbable Surgical Suture
Classification Name:	Absorbable poly(glycolide/L-lactide) surgical suture (per 21 CFR § 878.4493)

Indications for Use

Bondek Synthetic Absorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

Device Description

Bondek Synthetic Absorbable Surgical Suture is a sterile, absorbable, braided multifilament suture composed of a homopolymer of glycolic acid, polyglycolic acid. The suture material is coated with a polycaprolactone-glycerol monostearate solution.

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EXHIBIT I

510(k) Summary of Substantial Equivalence Cont.

BONDEK® Synthetic Absorbable Surgical Suture

Substantial Equivalence

The Bondek Synthetic Absorbable Surgical Suture is similar in intended use, materials, design, and performance characteristics to the Bondek Synthetic Absorbable Surgical Suture (#K905482 and #K930378), Ethicon, Inc. Vicryl® suture (#K946271, #K915835), and Lukens Medical Corp. Lukens® PGA suture (#K965162).

The determination of substantial equivalence for this device was based on a detailed device description, performance testing and conformance with voluntary performance standards, e.g. ISO 10993-1 Biological Evaluation of Medical Deices, U.S.P. Section 1475 - Absorbable Surgical Sutures, and the FDA Guidance Document *"Alternate Suture Labeling Resulting from January 11, 1993 Meeting with HIMA"*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 1999

Ms. Mary Gray
Regulatory Affairs Specialist
Genzyme Surgical Products Corp.
600 Airport Road
Fall River, Massachusetts 02720

Re: K991191
Trade Name: Bondek® Synthetic Absorbable Surgical Suture
Regulatory Class: II
Product Code: GAM
Dated: April 7, 1999
Received: April 8, 1999

Dear Ms. Gray:

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 that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Wednesday, September 18, 1991 (Vol. 56, No. 18, Pages 47150 and 47151). A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Bondek® Synthetic Absorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

2. This device may not be manufactured from any material other than homopolymers and copolymers made from glycolide and/or L-lactide. Any deviation of the polymer composition or processing as described in this 510(k) notification must be submitted to FDA in a new premarket notification at least 90 days prior to implementation of the proposed change(s). In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacturing of the Bondek® Synthetic Absorbable surgical suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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,

for 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

K991191

510(k) Number (if known)

Device Name

Bondek® Synthetic
Absorbable Surgical Suture

Indications for Use

Bondek® Synthetic Absorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991191

Prescription Use X
(Per 21 CFR § 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)