K984374

JUN 4 1999

Summary of Safety and Effectiveness Information

SAMYANG CORPORATION

Premarket Notification, Section 510(k)

MAY 26, 1999

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

Trade Name: *Surgisorb*

Common Name(s): Absorbable suture, synthetic absorbable suture, PGA suture

Classification Name(s): Suture, Absorbable, Synthetic, Polyglycolic Acid

2. Establishment Name & Registration Number:

Name: *SAMYANG CORPORATION*

Number: Pending

3. Classification:

PGA based suture is not specifically categorized or defined in 21CFR, Parts 800-1299. The responsible device panel provided the following class, classification panel and product code for this product.

Device Class: Class II

Classification Panel: General & Plastic Surgery Devices Panel

Product Code(s): 79GAM

4. Equivalent Predicate Device:

SAMYANG CORPORATION believes that *Surgisorb PGA Absorbable Suture* is substantially equivalent to the following absorbable suture marketed by Davis & Geck:

1 Dexon® II polyglycolic acid, synthetic absorbable surgical sutures with polycaprolate coating system.

With respect to substantial equivalence, the comparison device represents a virtually identical device. Materials, packaging, sterilization method, sizes, multi and monofiliment, dyed and undyed as well as functional characteristics (absorption rate, strength, etc.) Equivalency can also be drawn with respect to the design, material composition, performance and intended use. *Surgisorb* and Dexon® II both meet or exceed the performance requirements of USP 23.

5. Device Description:

Surgisorb brand absorbable suture is provided both dyed (D&C Violet #2) and undyed (milk white), braided and monofiliment types and coated with polycaprolate and calcium sterate.

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Sizes offered are U.S.P. 8.0 through 2 (metric equivalent 0.4 through 5). The brief table below illustrates the sizes offered.

USP Size (Metric Size)
8.0(0.4)
7.0(0.55)
6.0(0.7)
5.0 (1)
4.0(1.5)
3.0 (2)
2.0 (3)
0 (3.5)
1 (4)
2 (5)

Materials. Polyglycolic acid, U.S.P. & polycaprolate and calcium sterate.

Indications for Use. "General soft tissue approximation; including use in ophthalmic surgery, but not for use in cardiovascular and neurological tissue."

6. *Applicant Name & Address:*

SAMYANG CORPORATION
263 Yeonji-dong, Chongno-gu
Seoul 110-725, Korea

7. *Company Contact:*

Mr. Dong-Kee Yoo
SAMYANG CORPORATION
263 Yeonji-dong, Chongno-gu
Seoul 110-725, Korea
Tel. 011.82.2.740.7296
Fax 011.82.2.743.6626

8. *Submission Correspondent:*

Mr. David W. Schlorf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356 2640 - 925.356.2654 - fax

9. *Performance Standards:*

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include U.S.P., ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations.

SAMYANG CORPORATION also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

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10. *Special Controls:*

The following special controls apply to the marketing of this device when used as PGA based absorbable suture:

1. **Compliance with specified labeling requirements.** As outlined in the guidance "Alternate Suture Labeling Resulting from the January 11, 1993 Meeting with HIMA".

11. *Storage, Packaging & Sterilization Information:*

Packaging. Packaging should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of unsafe product and it should not be used until carefully inspected. If the package or product is damaged, the product should not be used and should be returned. Once opened, the product should never be resterilized or reused.

Storage. Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination. Rotate stock and observe shelf life dates. Discard when outdated or damaged. When used, the product must be placed into use following accepted surgical sterile technique.

Sterilization. The suture is terminally EtO gas sterilized.

12. *Summary Comparison Table:*

FEATURE	*Surgisorb*	*Davis & Geck*	SE?
Indications for Use:	GENERAL SOFT TISSUE APPROXIMATION; INCLUDING USE IN OPHTHALMIC SURGERY, BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUE.	SAME	YES
Design:	BRAIDED AND MONOFILIMENT	SAME	YES
Sterile:	YES - EtO	SAME	YES
Sizes:	USP - 8.0 THROUGH 2	SAME	YES
Material:	PGA	SAME	YES
Origin:	KOREA	USA	YES
Manufacturer:	SAM YANG	DAVIS GECK	YES
Product Code:	79GAM	SAME	YES
K - Number:	PENDING	PREAMENDMENT DEVICE	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 4 1999

SAMYANG Corporation
c/o Mr. David W. Schlerf
Buckman Company, Incorporated
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523

Re: K984374
Trade Name: Surgisorb Absorbable Suture
Regulatory Class: II
Product Code(s): GAM Suture, Absorbable, Synthetic, PolyGlycolic Acid (PGA)
Dated: March 20, 1999
Received: April 13, 1999

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosures) 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 Monday, December 11, 1989 (Vol. 54, No. 236, Pages 50737 and 50738). 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 devices subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Polygolycolic acid (PGA) Surgical Sutures are 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. The Polygolycolic acid (PGA) Surgical Sutures 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 sumitted to FDA in a new premarket notification at least 90 days prior to implementation of the proposed changes. 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 PGA 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 FDA clearance prior to commercial distribution of the modified device.

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

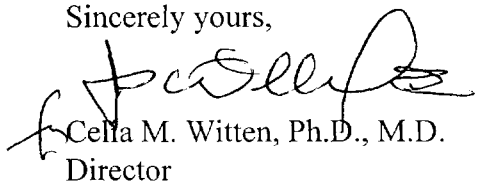
The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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) 594-4595. 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,



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

510(k) Number : **K984374**

Device Name(s): *SurgiSorb® Absorbable PGA Suture*

Intended Use(s) of the Device:

GENERAL SOFT TISSUE APPROXIMATION; INCLUDING USE IN OPHTHALMIC SURGERY, BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUE.

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 K984374

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional format 1-2-96)