MAY 1 8 1998

K980610

510k SUMMARY OF SAFETY AND EFFECTIVENESS

DEXON® "R" Polyglycolic Acid, Synthetic Absorbable Surgical Suture

Submitted by: Sherwood-Davis & Geck
444 McDonnell Blvd.
Hazelwood, MO 63042-2516

Contact: Vanada Johnson
Sr. Regulatory Affairs Specialist

Date of Summary: February 12, 1998

The Dexon® "R" Polyglycolic Acid Suture is an Absorbable Suture composed of a homopolymer of glycolic acid and coated with Polycaprolate, a copolymer of glycolide and epsilon-caprolactone. The Dexon "R" Suture is a Class II device, per 21 CFR Section 878.4493. Product code 73GAM. Performance standards have not been pulmogated for this device, as of this date..

The polycaprolate coating system is inert, noncollagenous, nonantigenic and nonpyrogenic. The Dexon "R" sutures are sterile, inert, noncollagenous, nonantigenic and nonpyrogenic and are available in various colors.

The Dexon® "R" Sutures are indicated for use in the surgical closure of skin and mucosa where short-term wound support is required and where rapid degradation of the suture material is considered desirable. It is not intended for use in ligation, ophthalmic, cardiovascular or neural tissue.

The following battery of tests were performed in accordance to respective guidelines and deemed acceptable: Cytoxicity (elution test), Systemic Injection, Pyrogenicity, Intracutaneous Injection and Strength Retention.

Dexon® "R" Polyglycolic Acid, Synthetic Absorbable Surgical Suture is substantially equivalent in design and composition to Vicryl Rapide (Ethicon, Inc.). Both are synthetic polyglycolic acid absorbable sutures. The intended use for Dexon "R" and Vicryl Rapide are very similar. Both are available sterile, undyed and in various lengths, diameters and quantities w/surgical needles. Sherwood-Davis & Geck considers the DEXON® "R" Polyglycolic Acid, Synthetic Absorbable Surgical Suture to be substantially equivalent to the DEXON family of predicate devices: DEXON II covered under 510(k) K900198, DEXON Violet covered under 510(k) K972566, Vicryl Rapide Suture covered under 510(k) K944110.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 1998

Ms. Vanada Johnson
Senior Regulatory Affairs Specialist
Sherwood Davis and Geck
444 McDonnell Boulevard
Hazelwood, Missouri 63042-2516

Re: K980610
Dexon R® Polyglycolic Acid Synthetic Absorbable Suture
Regulatory Class: II
Product Code: GAM
Dated: February 12, 1998
Received: February 17, 1998

Dear Ms. Johnson:

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 Tuesday, October 26, 1993 (Vol. 58, No. 205, Pages 57557 and 57558). 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 Dexon R® Polyglycolic Acid Synthetic Absorbable Suture is indicated for use in the surgical closure of skin and mucosa where only short-term wound support is required and where rapid degradation of the suture material is considered desirable. It is not intended for use in ligation, ophthalmic, cardiovascular, or neural tissues.

2. This device may not be manufactured from any material other than homopolymers and copolymers glycolide and/or L-lactide. 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 manufacture of the Dexon R® Polyglycolic Acid Synthetic Absorbable 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.

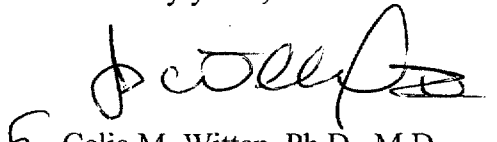
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) 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) 594-4595. 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 (if known) K980610

Device Name: Sherwood-Davis & Geck
DEXON® Rapid Polyglycolic Acid, Synthetic Absorbable Surgical Suture

Indications for Use: DEXON® Rapid (DEXON "R") sutures are indicated for use in the surgical closure of skin and mucosa where only short-term wound support is required and where rapid degradation of the suture material is considered desirable. It is not intended for use in ligation, ophthalmic, cardiovascular or neural tissue.

(PLEASE DO NO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrenc of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-off)

510(k) Number K980610