

510k Summary of Safety and Effectiveness

DEXON® Violet Polyglycolic Acid Suture

K 972-566

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

AUG 14 1997

Contact: Vanada Johnson
Regulatory Affairs Specialist

Date of Summary: July 8, 1997

DEXON® Violet Polyglycolic Acid Suture is a synthetic absorbable sterile surgical suture composed of homopolymers of glycolic acid and is a class II device, per 21 CFR Section 878.4493. Procode: 73GAM.

DEXON® Violet is a braided synthetic absorbable surgical suture composed of homopolymer of glycolic acid and coated with Polycaprolate, a copolymer of glycolide and epsilon-caprolactone and is indicated for use as an absorbable suture in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.

The DEXON® Violet Polyglycolic Acid Suture is an addition to the DEXON® family of Polyglycolic Acid Sutures and is sterile, inert, noncollagenous, nonantigenic and nonpyrogenic. DEXON Violet Polyglycolic Acid Sutures are available in various lengths, diameters and quantities with and without surgical needles.

The DEXON® Violet Polyglycolic Acid Suture elicits a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of the polyglycolic Acid sutures occur by means of hydrolysis, where the polymer degrades to glycolic acid and is subsequently absorbed and metabolized by the body.

The following battery of tests were performed in accordance to, and satisfied USP guidelines - Cytotoxicity, Pyrogenicity, Hemolysis, Sensitization, Mutagenicity, Acute Systemic Toxicity, Intracutaneous, Intramuscular Implant, Mammalian Mutagenicity, 6-Month Ambient Storage Stability and In-Vivo Strength Retention. Under Section 514 of the FD&C Act, performance standards have not been promulgated for this device at this time.

Sherwood-Davis & Geck considers DEXON® Violet Polyglycolic Acid Suture substantially equivalent to the predicate devices, the DEXON® Polyglycolic Acid Suture covered under 510(k) K951352, Dexon II Absorbable Suture covered under 510(k) K900198, Vicryl Braided (Polyglactin 910) Suture covered _____ and Polysorb Violet Suture



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG 14 1997

Re: K972566
Dexon® Violet Polyglycolic Acid Suture
Regulatory Class: II
Dated: July 8, 1997
Received: July 9, 1997

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 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 Dexon® Violet Polyglycolic Acid Suture 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 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 manufacture of the Dexon® Violet Polyglycolic Acid 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.

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

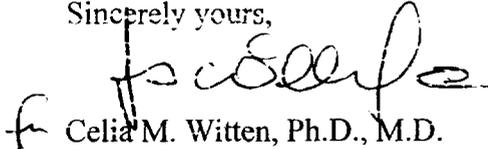
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibition against misbranding and adulteration.

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) 594-4639. 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,


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) K972566

Device Name: Sherwood-Davis & Geck
DEXON® Violet Polyglycolic Acid Suture

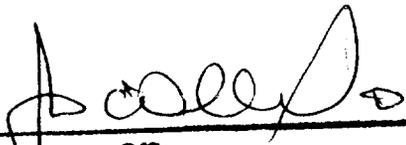
Indications for Use: The Polyglycolic Acid sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-off)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972566

510(k) Number _____