4/30/99

K982853

# 510k Summary of Safety and Effectiveness

**SILK NON-ABSORBABLE SURGICAL SUTURE (w/UV-10 adhesive)**

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

Contact: Vanada Johnson
Sr. Regulatory Affairs Specialist

Date of Summary: May 7, 1998

Silk Non-Absorbable Surgical Sutures are composed of the organic protein fibroin which is derived from the domesticated species Bombyx mori (B.mori) of the family Bombycidae. Silk Surgical Sutures were initially cleared, via the Premarket Notification process and assigned 510(k) file number K930586. Silk Non-Absorbable Surgical Sutures are a class II device, per 21 CFR Section 878.5030, with the Classification Code 80GAP.

Silk sutures are indicated for use as nonabsorbable sutures in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neural tissue. Silk sutures are braided or twisted and available in white or dyed (black or blue). Braided sutures (except for size 8/0) are coated with silicone. Silk sutures are also available in various lengths, diameters and quantities with or without surgical needles. SILK sutures are not absorbed, progressive degradation of the proteinaceous silk fiber in-vivo may result in gradual loss of all the suture's tensile strength over time.

Similarities between the proposed Silk suture and the currently marketed Silk Non-Absorbable Surgical are 1) both are composed of the organic protein fibroin, 2) both are sterile sutures, 3) both share the same indications for use, 4) both are available in the same various lengths, diameters, quantities, colors and sizes, 5) both are available with and without surgical needles and 6) both are packaged in identical Tyvek/Mylar packaging

The only difference between the proposed vs. the predicate Silk suture is an automated vs. a manual needle end stiffening process. The proposed Silk suture needle will be manufactured using an ***automated*** end stiffening process of applying the medical grade adhesive to a portion of the silk strand which is then cured and cut to length. The predicate Silk suture needle is currently manufactured using a ***manual*** end stiffening process of winding the suture material onto racks and dipping the end in a nylon resin bath, curing then cutting the suture to length.

K982853

**Summary of Safety and Effectiveness**
**SILK NON-ABSORBABLE SURGICAL SUTURE**

Silk Non-Absorbable Surgical Sutures, with adhesive, were tested for biocompatibility in accordance to ANSI/AAMI 10993. Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". Further, the following battery of tests were performed in accordance to USP guidelines - Cytotoxicity, Hemolysis, Sensitization, Acute Systemic Toxicity, Irritation, Intracutaneous.

Sherwood-Davis & Geck considers the proposed Silk Surgical Suture (w/adhesive) to be substantially equivalent in design, composition and intended use, to the currently marketed Silk Suture covered under K930590.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1999

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

Re: K982853
Trade Name: Silk Suture
Regulatory Class: II
Product Code: GAP
Dated: December 29, 1998
Received: February 12, 1999

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 Silk Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

2. This device may not be manufactured from any material other than multifilamentous fibers composed of fibroin, an organic protein that is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. 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 Silk 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,

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

K982853



510(k) Number (if known)

Device Name: Sherwood-Davis & Geck
**Silk Nonabsorbable Surgical Suture**

Indications for Use:

Silk sutures are indicated for use as nonabsorbable sutures in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982853

510(k) Number _____