JUL 13 1998

510k Summary of Safety and Effectiveness

K981582

SURGILON® (Polyamide) , OPHTHALON®, AND DERMALON® NON-ABSORBABLE SURGICAL SUTURE

Submitted by: Sherwood-Davis & Geck
4444 McDonnell Blvd.
Hazelwood, MO 63042-2516

Contact: S. Tamsett, Manager

Date of Summary: July 7, 1998

Surgilon (polyamide) Ophthalon and Dermalon Non-Absorbable Surgical Suture are braided and monafilanent suturs with a silicone coated dyed white or black with Logwood extract. These surgical sutures are composed of a long-chain aliphatic polymer Nylon 6 or Nylon 6,6. Surgilon, Dermalon and Ophthalan sutures are a class II device per 21 CFR Section 878.5020. Classification Code: 80GAR.

Sugilon (polyamide), Opthhalon, and Dermalon sutures are indicated for use as non-absorbable sutures in general soft tissue approximation and/or ligation, including use in Cardiovascular, Ophthalmic and Neural tissue. These sutures are braided and monofilament sutures available in various lengths, diameters and quantities with or without surgical needles. They are not absorbed, progressive hydrolysis of the nylon in-vivo may result in gradual loss of tensile strength over time.

Similarities between the proposed Surgilon, Ophthalon, and Demalon sutures to currently marketed sutures are 1)all are composed of long-chain aliphatic polymer, 2)all are sterile sutures, 3)all share the same indications for use, 4) all are available in the same lengths, diameters, quantities, colors and sizes, 5) all are available with and without surgical needles and 6)all are packaged in identical Tyvek/Mylar packaging.

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

Summary of Safety and Effectiveness

These representative 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, surgical sutures meet all requirements established by the United States Pharmacopeia (SP) and European Pharmacopoeia (EP) for surgical sutures.

Sherewood-Davis & Geck considers the proposed Surgilon, Ophthalon ,and Dermalon Surgical Sutures (w/adhesive) to be substantially equivalent in design, composition and intended use, to the currently marketed Surgilon, Dermalon, Ophthalon non-absorbable sutures covered under K930586.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 1998

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

Re: K981582
Trade Name: Surgilon, Dermalon, Ophthalon & Ophthalmic Non-Absorbable Nylon Suture
Regulatory Class: II
Dated: May 1, 1998
Received: May 4, 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 Friday, May 31, 1991 (Vol. 56, No. 105, Pages 24684 and 24685). 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 Surgilon, Dermalon & Ophthalon & Ophthalmic Non-Absorbable Nylon Surgical 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 long chain aliphatic polymers other than nylon 6 and/or nylon 6,6. 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 Surgilon, Dermalon & Ophthalon & Ophthalmic Non-Absorbable Nylon 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.

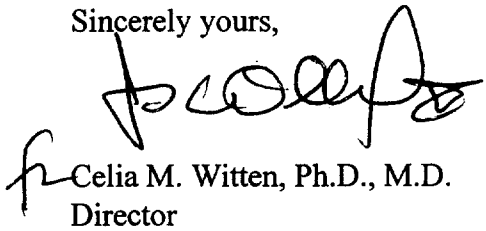
The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

The general controls provisions of the Act include requirements for 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)

Device Name:

Surgilon/Polyamide, Dermalon, Ophthalon and Ophthalmic Nylon Non-absorbable Surgical Suture

Indications for Use:

Indicated for use as non-absorbable sutures in general soft tissue approximation and/or ligation, including use in Cardiovascular, Ophthalmic and Neural tissue. Surgilon (polyamide), Dermalon, Ophthalon are both braided and monofilament sutures available in white or dyed (black or blue) with a Logwood extract. These sutures are available in various lengths, diameters and quantities with or without surgical needles. These sutures are not absorbed, progressive hydrolysis of the nylon in-vivo may result in gradual loss of its tensile strength.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Division Sign-Off)

510(k) Number K981582
