3/15/99

K990089

VII. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted By

Steve Reitzler, RAC
Regulatory Consultant to AESCULAP®
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San Diego, California 92130
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AESCULAP®
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Telephone: (650) 876-7000
Contact: Victoria Mackinnon, Director of Regulatory Affairs & Quality Assurance
Date Prepared: January 7, 1999

B. Device Name

Trade or Proprietary Name:	*Silkam*® Nonabsorbable Silk Surgical Suture
Common or Usual Name:	Nonabsorbable Silk Surgical Suture
Classification Name:	Natural Nonabsorbable Silk Surgical Suture

C. Predicate Devices

- Perma-Hand® Nonabsorbable Silk Surgical Suture (Ethicon, Inc.)
- Nonabsorbable Silk Surgical Suture (Davis & Geck)
- SOFSILK® Nonabsorbable Silk Surgical Suture (U. S. Surgical Corp.)

The subject device is substantially equivalent to predicate devices listed above.

D. Device Description

The subject device is a nonabsorbable, sterile, flexible, braided multifilament thread composed of an organic protein called fibroin. It is derived from the domesticated silkworm species *Bombyx mori*, of the family *Bombicidae*, and is indicated for general soft tissue approximation and/or ligation. It meets all applicable requirements of the U. S. Pharmacopeia Official Monograph for Nonabsorbable Surgical Sutures (Class I). It will be offered undyed, and dyed with the FDA listed colorant Logwood extract in accordance with Title 21 CFR, §73.1410. It will be offered uncoated, or with a coating to enhance certain characteristics. It will be available with and without standard needles attached.

E. Intended Use

Silkam® sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

F. Comparison to Predicate Devices

The subject *Silkam*® Nonabsorbable Silk Surgical Suture is composed of the same material as are the predicate devices, that being the organic protein fibroin in the form of degummed silk derived from domesticated *B. mori*. Further, as are the predicate devices, the subject device is offered undyed, and dyed with Logwood extract, or hematein, at a concentration of ≤1.0% by suture weight in accordance with Title 21 CFR, §73.1410. In addition, as are the predicate devices, the suture is offered both uncoated, or treated with a biocompatible coating to enhance its handling properties.

The subject device has the same design as do the predicate devices, being a sterile, flexible, braided multifilament thread which is offered in a variety of lengths and a range of diameters conforming with the requirements of U.S. Pharmacopeia (U.S.P.) XXIII, and which is offered with or without one of a selection of standard needles attached. Further, as is the case with the predicate devices, the subject device conforms in all respects to the requirements of the Official Monograph for Nonabsorbable Surgical Suture in U.S.P. XXIII, including <861> *Sutures -- Diameter*, <871> *Sutures -- Needle Attachment*, and <881> *Tensile Strength*.

Physical properties of the subject device are substantially equivalent to those of the predicate devices, including fiber diameter, knot pull tensile strength, knot security, capillarity, and needle attachment strength.

The subject device is manufactured in the same manner as the predicate devices, being produced from degummed and bleached yarns of natural silk harvested through sericulture of B. mori, and braided in operations considered standard in the fiber industry to form the finished suture fiber. As such, the suture fiber from which the subject device is made has essentially the same physical and chemical properties, and hence, biosafety profile and *in vivo* performance characteristics, as do the predicate devices.

The subject device is packaged and sterilized in the same or equivalent manner, and has the same labeling claims, as do the predicate devices.

G. Summary of Non-Clinical Tests

Non-Clinical testing conducted on the subject device to demonstrate its substantial equivalence to predicate devices included physical testing for all parameters identified above and to prove conformance to the requirements of U.S.P., *in vitro* and *in vivo* biosafety studies, and 12 and 24 month implant studies in animals to demonstrate retention of tensile strength.

H. Summary of Clinical Tests

(Not applicable)

I. Conclusions of Non-Clinical and Clinical Tests

The results of all testing demonstrated the substantial equivalence, if not superiority, of the subject device to one or more predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 1999

Mr. Steve Reitzler
Regulatory Consultant to AESCULAP®
13221 Maricotte Place
San Diego, California 92130

Re: K990089
Trade Name: *Silkam®* Nonabsorbable Silk Surgical Suture
Regulatory Class: II
Product Code: GAP
Dated: January 7, 1999
Received: January 11, 1999

Dear Mr. Reitzler:

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 *Silkam®* Nonabsorbable 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 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 *Silkam®* Nonabsorbable 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.

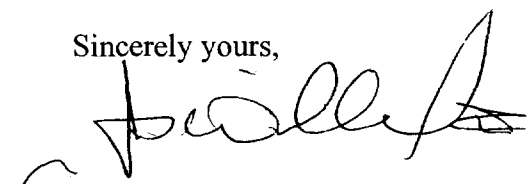
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibition against misbranding and adulteration.

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

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): K990089

Device Name: *Silkam*® Nonabsorbable Silk Surgical Suture

Indications for Use:

Silkam® *sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.*

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K990089

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)