FEB 4 2000

K993999

T.CAD International
991002/MG-510(k)
SILK

SECTION III

510(K) Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and Title 21 CFR §807.92

A. Applicant & Submitted By:

Trading Consultants And Distributors International Inc.
(T.CAD International)
157 WindDance Dr.
Chicago, IL 60046-6681
Telephone: (847) 265-7676
Fax. : (847) 265-7686

Contact Person: Main M. Ghazal, President
Date Prepared: October 2nd 1999.

B. Device Name:

a. Trade Name: SILK
b. Common or Usual Name: Silk Surgical Suture, Nonabsorbable
c. Classification Name: Natural nonabsorbable silk surgical suture (Per 21CFR878.5030)

C. Predicate Device:

Silk Non-Absorbable Surgical Sutures of Davis & Geck (K930590)

D. Device Description:

SILK is a nonabsorbable, sterile, flexible multifilament thread composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae.
SILK is offered braided, uncoated or silicon coated, undyed or dyed with an FDA listed color additive, D&C Blue No. 9 (21CFR74.1109), or Logwood extract, C.I. Natural Black 1 (21CFR74.1410). SILK meets the United States Pharmacopeia (U.S.P.) monograph requirements for nonabsorbable silk surgical sutures.

E. Intended Use:

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

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F. Comparison to Predicate Device:

	SILK	Predicate Device
Intended Use	General soft tissue approximation and /or ligation, including use in cardiovascular, ophthalmic and neurological procedures.	General soft tissue approximation and /or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
Suture Material	Natural Organic Protein (Fibroin). Braided or Twisted, available in White (Virgin) or Dyed (Black or Blue).	Natural Organic Protein (Fibroin). Braided or Twisted, available in White (Virgin) or Dyed (Black or Blue).
Suture Characteristics	Not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of all of the suture's tensile strength over time.	Not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of all of the suture's tensile strength over time.
Sterilization Method	Gamma Irradiation	Same of equivalent process
How Supplied	Sterile and offered for Single Use Only. Braided, uncoated or coated, undyed or dyed with an FDA listed color additive. Available with or without surgical needle.	Same or equivalent manner. Predicate device is offered braided, coated with silicon, undyed or dyed with the same FDA listed colorants.
Suture Diameter, Suture Length, Knot Pull Tensile Strength and Needle Attachment Strength	Meet U.S.P. Requirements	Meet U.S.P. Requirements
Packaging	Dry packaged in Aluminum Foil and Polyester tear open packaging.	Dry packaged in Tyvek/Mylar
Labeling	In conformance with CDRH instructions of the "Medical Device Quality Manual" dated December 1996. Package Inserts in accordance with the FDA Guidance documents " Alternate Suture Labeling" Resulting from the January 11th 1993 meeting with HIMA, reformatted on December 17th 1997.	Same.

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G. Clinical & Non-Clinical Testing:

Non-Clinical Testing was conducted on the subject device to prove conformance to the requirements of U.S.P. standards and to demonstrate substantial equivalence to the predicate device. Physical properties and functionality testing assured the safety and effectiveness of the subject device within its intended uses. Results of the non-clinical testing demonstrate conformance with the U.S.P. standards and requirements for Absorbable surgical suture.

Clinical Testing: Not available at the present time.

H. Conclusion:

Based on the detailed device description, the intended use of the device, the technological characteristics and physical properties of the device, performance testing and conformance with voluntary performance standards like:

a. United States Pharmacopeia Standards
b. ISO 9002, EN 46002 & EN 552 Standards
c. FDA Guidance documents " Alternate Suture Labeling" Resulting from the January 11th 1993 meeting with HIMA.

T.CAD International believes that the subject device demonstrates a substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

Mr. Main M. Ghazal
Trading Consultants and Distributors International, Inc.
157 WindDance Drive
Chicago, Illinois 60046-6681

Re: K993999
Trade Name: Silk
Regulatory Class: II
Product Code: GAP
Dated: November 22, 1999
Received: November 24, 1999

Dear Mr. Ghazal:

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 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. 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.

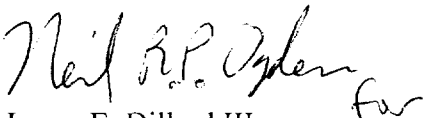
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibition against misbranding and adulteration.

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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K993999

T.CAD International
991002/MG-510(k)
SILK

SECTION II

Statement of indication for use

Device Name: SILK

510(k) Number:

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

(PLEASE DO NOT WRITE BELOW THE LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

NRO for JZD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993999