K041514
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JUN 3 2005

SUTURES INDIA PVT.LTD
SUBMISSION OF PREMARKET NOTIFICATION (510K) FOR NATURAL NONABSORBABLE SILK SURGICAL SUTURE

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510K SUMMARY as required by: 21CFR 807.92

A. APPLICANT INFORMATION

Name : SUTURES INDIA PVT. LTD

Address : Sutures India Pvt. Ltd.
118, 3rd Phase, Peenya Industrial Area,
Bangalore–560058. India

PH.NO. : 91-80-28395150 / 28370367 / 28377856
FAX NO :91-80-28392280.

E mail : sutures@vsnl.com
Web address : www.suturesin.com

B. Contact Person : L.G.Chandrasekhar
: MANAGING DIRECTOR

C. Date Prepared : May 15,2004

D. DEVICE TRADE NAME

- Trade Name : TRUSILK
- Common name : Nonabsorbable Surgical Suture, U.S.P. (Black Braided Silk)
- Classification Name :Natural Nonabsorbable Silk Surgical Suture.

E. PREDICATE DEVICES

- Silkam Nonabsorbable surgical suture, 510(k) Number K990089, AESCULAP, South San Fransisco, California.
- Silk Nonabsorbable surgical suture, 510(k) Number K960328. R.K.Medical L.L.C, Danbury , CT06810

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F. DESCRIPTION OF THE DEVICE

TRUSILK is a natural nonabsorbable silk surgical suture, 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. Natural Nonabsorbable silk surgical suture meets the United States Pharmacopeia (U.S.P.) monograph requirements for "Nonabsorbable Surgical Suture" . Natural Nonabsorbable silk surgical suture may be braided or twisted; it may be provided uncoated or coated; and it may be undyed or dyed with an FDA listed color additive. It will be available with and with out a standard needle attached.

G. INTENDED USE OF THE DEVICE

Sutures India TRUSILK Natural nonabsorbable silk suture, is indicated for use in soft tissue approximation and/ or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

COMPARISON TABLE SUTURES INDIA'S "TRUSILK" NATURAL SILK NONABSORBABLE SURGICAL SUTURE TO PREDICATE DEVICES

Comparison items	Sutures India Pvt.ltd	Aesculap	R.K.Medical
Natural Nonabsorbable silk surgical suture 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.	Same	Same	Same
The sutures are inert, noncollageneous and nonantigenic.	Same	Same	Same
Natural nonabsorbable silk surgical suture is available undyed or dyed with logwood extract	Same	Same	Same
Natural nonabsorbable silk surgical suture is offered both uncoated, and treated with biocompatible coatings to enhance its handling properties.	Same	Same	Same
Natural Nonabsorbable silk suture is indicated for use in soft tissue approximation and/ or ligation, including use in cardiovascular, ophthalmic and neurological procedures.	Same	Same	Same

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Comparison items	Sutures India Pvt.ltd	Aesculap	R.K.Medical
Natural nonabsorbable sterile silk suture is supplied for single use only.	Same	Same	Same
Natural nonabsorbable sterile silk suture is sterilized by EO method	Same	Same	Same
Natural nonabsorbable silk suture is packaged in the same or equivalent manner, and has the same or equivalent labeling claims as the predicate devices including indications, warnings, cautions and precautions	Same	Same	Same
Natural nonabsorbable silk suture meets the Official Monograph of the United States Pharmacopeia current edition USP26 for extractable color	Same	Same	Same
Finished suture material meets the performance requirements defined in the United States Pharmacopeia current edition USP26 for Diameter<861>	Same	Same	Same
Finished suture material meets the performance requirements defined in the United States Pharmacopeia current edition USP26 for Tensile strength<881>	Same	Same	Same
Finished suture material meets the performance requirements defined in the United States Pharmacopeia current edition USP26 for Needle attachment<871>	Same	Same	Same
Natural nonabsorbable silk suture meets the Official Monograph of the United States Pharmacopeia current edition USP26 for Sterility	Same	Same	Same
Finished suture material packaged in a same or equivalent manner with sterile single or double packing having labeling conforming to 21CFR and USP 26	Same	Same	Same
Nonabsorbable Surgical Suture (Braided Silk Black) is biologically compatible when tested as per ISO-10993	Same	Same	Same

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SUBMISSION OF PREMARKET NOTIFICATION (510K) FOR
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CONCLUSION

Sutures India's TRUSILK is Natural Nonabsorbable silk suture, composed of the same material, as are the predicated devices and has the same design, as do the predicate devices. The suture is manufactured in a manner typical of the industry and equivalent to that used to produce predicate devices. Further the subject device is offered with the same colorant Logwood extract at a concentration that conforms to the requirements of Title 21 CFR § 73.1410, as are of the predicate devices.

Testing of suture diameter, suture length, knot pull tensile strength and needle attachment strength, extractable color and sterility to methods outlined in USP 26 demonstrates Sutures India's TRUSILK, Natural Nonabsorbable silk suture meets or exceeds USP specifications and are equivalent in terms of the above mentioned predicate devices.

L.G.Chandrasekhar
Managing Director

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 2005

Mr. L.G. Chandrasekhar
Managing Director
Sutures India Private Limited
472 D, 13th Cross, 4th Phase
Peenya Industrial Area,
Bangalore 560058, India

Re: K041514
Trade/Device Name: TRUSILK™ Non-absorbable Silk Surgical Suture
Regulation Number: 21 CFR 878.5030
Regulation Name: Natural nonabsorbable silk surgical suture
Regulatory Class: II
Product Code: GAP
Dated: May 3, 2005
Received: May 6, 2005

Dear Mr. Chandrasekhar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041514

Device Name: TRUSILK™ Non-absorbable Silk Surgical Suture

Indications For Use:
TRUSILK™ Non-absorbable Silk Surgical Suture is indicated for use in soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures.

Prescription Use ____x__ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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