K041511

JUN 3 - 2005

SUTURES INDIA PVT.LTD
SUBMISSION OF PREMARKET NOTIFICATION (510K) FOR NONABSORBABLE POLYPROPYLENE 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 07,2004

D. DEVICE TRADE NAME

- Trade Name : TRULENE
- Common name : Nonabsorbable Surgical Suture, U.S.P. (Monofilament Polypropylene)

- Classification Name : Nonabsorbable Polypropylene Surgical Suture

E. PREDICATE DEVICES

- Polypropylene Nonabsorbable surgical suture, 510(k) Number K001185, C.P.Medical, Portland, OR 97232.
- Polypropylene Nonabsorbable surgical suture, 510(k) Number K961389. R.K.Medical L.L.C, Danbury, CT 06810

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F. DESCRIPTION OF THE DEVICE

TRULENE Nonabsorbable polypropylene surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene.

The polypropylene surgical suture meets united states pharmacopeia (U.S.P.) requirements as described in the U.S.P. monograph for nonabsorbable surgical sutures; it is dyed with an FDA approved color additive (Phthalocyaninato (2-) copper); and the suture is provided with a standard needle attached.

G. INTENDED USE OF THE DEVICE

Sutures India TRULENE Polypropylene Nonabsorbable Surgical Suture is indicated for use in soft tissue approximation and / or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

COMPARISON TABLE SUTURES INDIA "TRULENE" NONABSORBABLE SURGICAL SUTURE (POLYPROPYLENE) TO PREDICATE DEVICES

Comparison items	Sutures India Pvt. Ltd	CP Medical	R.K.Medical
Nonabsorbable polypropylene surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene.	Same	Same	Same
The sutures are inert, noncollageneous and nonantigenic.	Same	Same	Same
Polypropylene Nonabsorbable Surgical Suture is available undyed or dyed with (Phthalocyaninato (2-) copper)	Same	Same	Same
Polypropylene Nonabsorbable Surgical Suture may be provided with or without a standard needle attached.	Same	Same	Same
Polypropylene Nonabsorbable Surgical 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	C.P. Medical	R.K.Medical
Polypropylene Nonabsorbable Surgical Suture is supplied for single use only.	Same	Same	Same
Polypropylene Nonabsorbable Surgical Suture is sterilized by EO method	Same	Same	Same
Polypropylene Nonabsorbable Surgical 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
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
Polypropylene Nonabsorbable Surgical 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 finish suture Length Requirement (95% of stated label length)	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
Polypropylene Nonabsorbable Surgical Suture is biologically compatible when tested as per ISO-10993	Same	Same	Same

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CONCLUSION

Sutures India "TRULENE" Polypropylene nonabsorbable surgical suture is 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 (Phthalocyaninato (2-) copper) at a concentration that conforms to the requirements of Title 21 CFR § 73.8045, as are of the predicate devices.

Testing of suture diameter, suture length, knot pull tensile strength, extractable color, needle attachment strength and sterility to methods outlined in USP 26 demonstrates Sutures India "TRULENE" Polypropylene nonabsorbable surgical 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: K041511
Trade/Device Name: TRULENE™ Non-absorbable Polypropylene Surgical Suture
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: GAW
Dated: May 26, 2005
Received: June 1, 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) 276-0115 . 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): K041511

Device Name: TRULENE™ Non-absorbable Polypropylene Surgical Suture

Indications For Use:
TRULON™ Non-absorbable Polypropylene 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)

...ion of ...l, Restorative
... Neurological Devices

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