

JUL 26 2006

K060018

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510 (k) SUMMARY OF INFORMATIONS, AS REQUIRED BY 21 CFR 807.92 REGARDING PERFORMANCE, SAFETY AND EFFECTIVENESS UPON WHICH AN EQUIVALENCE DETERMINATION CAN BE MADE.

A. APPLICANT INFORMATION

Name of the Manufacturer : SUTURES INDIA PVT.LTD.
Address : 472 D, 13 th Cross, 4 th Phase,
Peenya Industrial Area,
Bangalore 560058, India.
Phone Number : 91-80-41868000 to 8030 (30 lines)
Fax Number : 91-80-41171056
E.Mail : sutures@suturesin.com
Web Address : www.suturesin.com

B. OFFICIAL CORRESPONDENT : L.G.Chandrasekhar
Managing Director

C. DEVICE NAME

Trade Name : **TRULENE MESH**
Common Name : Nonabsorbable Polypropylene Surgical Mesh
Classification Name : Mesh Surgical Polymeric

D. PREDICATE DEVICES:

(1) Device Name: Nonabsorbable Polypropylene Surgical Mesh
510(k) Number: K 905655

Manufacturer: United States Surgicals, A Division of Tyco Health,
150, Glover Ave, Norwalk CT 06856

(2) Device Name (Proprietary): Minimesh
Generic / Common Name: Polymeric Surgical Mesh
510 (k) Number : K 041632

Manufacturer: Mpathy Medical Devices Ltd,
150, Aran Hill road, Fairfield, CT 06824 1712

E. REGULATION NUMBER: 878.3300 PRODUCT CODE: FTL

E. DESCRIPTION OF THE DEVICE:

Trulene Mesh is Nonabsorbable Polypropylene Surgical Mesh, produced by knitting filaments of extruded undyed Monofilament Polypropylene, a synthetic linear Polyolefin.

F. INTENDED USE OF THE DEVICE:

Trulene mesh may be used for the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

COMPARISON TABLE SUTURES INDIA'S "TRULENE MESH"
NONABSORBABLE SURGICAL MESH (POLYPROPYLENE) TO PREDICATE
DEVICES

Comparison items	Sutures India	United States Surgicals.	MPathy Surgical
Raw Material used: Undyed Monofilament Nonabsorbable polypropylene, flexible thread prepared from long-chain polyolefin polymer known as Polypropylene .	Same	Same	Same
U.S.P. Size of the Polypropylene thread	5-0	Same	Same
Diameter of the raw material (Metric Size)	0.1 to 0.149 mm	Same	Same
Knot Pull Tensile Strength of raw material	NLT 0.5 Kgf	Same	Same
Linear Tensile Strength of raw material	0.75 +/- 0.05 Kgf	Same	Same
Trulene mesh may be used for the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.	Same	Same	Same

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Comparison items	Sutures India	Ethicon	U.S.Surgicals
Trulene Polypropylene Nonabsorbable Surgical Mesh is supplied for single use only	Same	Same	Same
Trulene Polypropylene Nonabsorbable Surgical Mesh is sterilized by E.O. method	Same	Same	Same
Trulene Polypropylene Nonabsorbable Surgical Mesh is packed 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
Thickness of the Trulene Mesh is	0.44 – 0.46 mm	approximately the same	approximately the same
Density of the Trulene Mesh is	95 Gram per Sq. Meter	approximately the same	approximately the same
Pore Size of the Trulene Mesh:	22 to 23 Pores per inch	approximately the same	approximately the same
Tensile Strength of Trulene Mesh:	14.0 to 16.0 Kgf	approximately the same	approximately the same
Burst Strength of Trulene Mesh:	12.0 to 13.0 Kg/S.Cm	approximately the same	approximately the same
Tear resistance of Trulene Mesh	5.0 to 6.5 Kgf	approximately the same	approximately the same
Suture Pull out Strength	6.25 to 7.5 Kgf	approximately the same	approximately the same
Trulene Polypropylene Nonabsorbable Surgical Mesh is biologically compatible when tested as per ISO-10993 standards	Same	Same	Same

CONCLUSION

Trulene Polypropylene Nonabsorbable surgical Mesh is composed of the same material, as are the predicate devices and has similar knit design, as do the predicate devices. The mesh is manufactured in a manner typical of the industry and equivalent to that used to produce the predicate devices.

Testing of Trulene Mesh and the substantially equivalent devices for the parameters, viz, Thickness, Density, Pore Size, Burst Strength, Tensile Strength, Tear Resistance, cleanliness, Sterility requirements demonstrates that "TRULENE" Polypropylene Nonabsorbable surgical suture meets or exceeds the requirements and are equivalent in terms of the above mentioned predicate devices.

L.G.Chandrasekhar
Managing Director



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2006

Sutures India Pvt. Ltd.
% L.G. Chandrasekhar
Managing Director
472-D, 13th Cross, 4th Phase
Peenya Industria Area
Bangalore – 560 058
India

Re: K060018

Trade/Device Name: TRULENE MESH
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 14, 2006
Received: June 19, 2006

Dear L.G. 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.

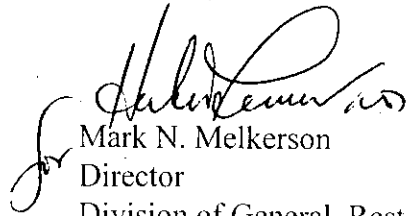
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) No. : K 060018

DEVICE NAME : TRULENE MESH
NONABSORBABLE POLYPROPYLENE SURGICAL MESH

INDICATIONS FOR USE:

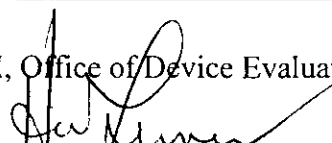
TRULENE MESH, NONABSORBABLE POLYPROPYLENE SURGICAL MESH IS INDICATED FOR USE IN HERNIA REPAIR AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.

Prescription Use (Part 21 CFR 801 Subpart D)

AND / OR

Over -The - Counter Use (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative, and Neurological Devices, Page 1 of 1

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