K070243

VISIONARY MEDICAL SUPPLIES, INC.
OPHTHALMIC SUTURES, IOLs AND MORE

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510(K) Summary

APR 17 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92

The assigned 510(k) number is:_____.

Applicant:

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Contact Person:

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Date of 510(k) summary preparation: January 24, 2007

Trade name: Sutralene Polypropylene Sutures

Common name: Suture, nonabsorbable, synthetic, polypropylene

Predicate devices:
The nonabsorbable Sutralene Polypropylene Sutures manufactured for Visionary Medical Supplies are equivalent to Ethicon PROLENE* nonabsorbable polypropylene sutures. The Ethicon PROLENE Nonabsorable polypropylene sutures were approved by PMA N16374. Subsequent to the PMA, polypropylene sutures were down classified and require clearance to market by 510(k),

1.0 Device description:

This Sutralene Polypropylene Suture is a nonabsorbable, sterile, surgical suture composed of a strand of polypropylene, a synthetic linear polyolefin. Those dyed blue are dyed with phthalocyaninato(2-) copper in accordance with Title 21 CFR Part 74.3045 and do not exceed 0.5% (w/w) suture. The sutures are uncoated.

2.0 Intended use:

The nonabsorbable Sutralene Polypropylene Suture manufactured for Visionary Medical Supplies is intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.

3.0 Performance tests to demonstrate substantial equivalency:

To establish the technical equivalency of nonabsorbable sutures manufactured for Visionary Medical Supplies with predicate devices, tests were conducted for diameter, tensile strength, and suture-needle attachment according to methods presented in United States Pharmacopoeia (USP) Monograph for nonabsorbable surgical sutures.

The test results shows that Visionary Medical Supplies' devices tested meet USP standards and are technically equivalent to the predicate devices tested.

4.0 Conclusions

The intended use, technology and materials of the Visionary Medical Supplies Sutralene Polypropylene Suture are the equivalent to the predicate device. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Visionary Medical Supplies, Inc.
% Quality & Regulatory Associates, LLC
Mr. Gary Syring
Principal Consultant
800 Lavenger Lane
Stoughton, Wisconsin 53711

APR 17 2007

Re: K070243
Trade/Device Name: Sutralene Polypropylene Sutures
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable propylene surgical suture
Regulatory Class: II
Product Code: GAW
Dated: March 15, 2007
Received: March 19, 2007

Dear Mr. Syring:

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) Number (if known): _____

Device Name: Sutralene Polypropylene Sutures

Indications for Use:

The Sutralene polypropylene nonabsorbable sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k070243

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)