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

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www.visionarymedicalsupplies.com

510(K) Summary

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:

Visionary Medical Supplies, Inc.
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Contact Person:

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Date of 510(k) summary preparation: September 3, 2010

Trade name: Sutrazorb Absorbable PGA Sutures

Common name: Absorbable Poly(glycolide/l-lactide) Surgical Suture

Predicate devices:

Trade Name: DEXON II
Manufacture: Davis & Geck
PMA Number: K951352

Trade Name: Surgisorb
Manufacture: Samyang Corporation
510(k) Number: K984374

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1.0 Device description:

The Sutrazorb Absorbable PGA Suture (Sutrazorb Suture) is a sterile, surgical suture composed of monofilaments and braids of polyglycolic acid. The suture is dyed violet. The violet sutures are dyed with D&C Violet #2 in accordance with CFR Title 21 Part 74.3602, reference Section 6.0.

The Visionary Medical Supplies' Sutrazorb Suture meets all requirements established by the United States Pharmacopoeia for absorbable surgical sutures. Testing to the following USP 32:2009 Monographs for Absorbable Sutures is discussed in Section 6.0:

- Sutures – Diameter <861>
- Sutures – Needle Attachment <871>
- Tensile Strength <881>

2.0 Intended use:

Sutrazorb Absorbable Surgical Sutures USP / EP are indicated for use in general soft tissue approximation and / or ligation in ophthalmic procedures. The safety and effectiveness of Sutrazorb sutures in cardiovascular and neurological procedures have not been established.

3.0 Performance tests to demonstrate substantial equivalency:

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

Absorption profile and shelf life tests were also performed. The test results shows that Sutrazorb Sutures 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 Sutrazorb Sutures 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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Visionary Medical Supplies, Inc.
% Quality and Regulatory Associates, LLC
Mr. Gary Syring
800 Levanger Lane
Stoughton, Wisconsin 53589

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Re: K102592
Trade/Device Name: Sutrazorb Absorbable PGA Sutures
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L- lactide) surgical suture
Regulatory Class: II
Product Code: GAM
Dated: January 18, 2011
Received: January 21, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K102592

Device Name: Sutrazorb Absorbable PGA Sutures

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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)

David Krum for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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