DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 2, 2017

Myco Medical
c/o Mr. E. J. Smith
Smith Assoicates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K161737
Trade/Device Name: Reli Redidiox Dyed, Reli Redidiox, Reli Redidiox Undyed
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: January 31, 2017
Received: February 1, 2017

Dear Mr. Smith:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161737

Device Name
REDIDIOX SUTURE

Indications for Use *(Describe)*
The REDIDIOX Suture is used in soft tissue approximation, including use in ophthalmic surgery, but not for use in cardiovascular and neurological tissues.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

SPONSOR
Company Name: Myco Medical
Company Address: 158 Towerview Court
Cary, North Carolina 27513

Telephone: 919-460-2535

Contact Person: Sanjv Kumar

Summary Prepared February 27, 2017

Trade Name: Redidiox™ REDIDIOX Monofilament Polydioxanone Absorbable Suture
Common/Usual Name: Surgical Sutures
Classification Name: Absorbable polydioxanone surgical suture
Product Code: NEW
Device Class: Class II
Regulation Number: 21 CFR 878.4840

Predicate Device

Company	***Product***	***510(k) #***
Sutures India Pvt Ltd	PD SYNTH	K081001

Device Description

The REDIDIOX is a (Polydioxanone) monofilament synthetic absorbable suture prepared from the polyester poly (p-dioxanone). The empirical molecular formula of the polymer is ($C_4H_6O_3$). Polydioxanone polymer has been found to be nonpyrogenic and elicits only a slight tissue reaction during absorption. Based on absorption study it takes 182 days for total absorption. The monofilament material is available undyed and dyed. The dyed material is colored violet, dyed with D&C Violet. REDIDIOX sutures comply with USP requirements, except for diameter.

Indications for Use

The REDIDIOX Suture is used in soft tissue approximation, including use in ophthalmic surgery, but not for use in cardio vascular and neurological tissues.

Summary of Technological Characteristics

Parameters	**Myco Medical**	**Predicate device: PD Synth**	**Comment**
510(k) Number	**N/A**	**K081001**	

Indications for Use	The REDIDIOX Suture is used in soft tissue approximation, including use in ophthalmic surgery, but not for use in cardio vascular and neurological tissues.	Indicated for use in soft tissue approximation, including use in opthalmic procedures, but not for use in cardiovascular and neurological procedures.	**Identical**
Suture is a synthetic absorbable surgical suture. It is a sterile flexible monofilament thread, composed of polydioxanone. The sutures are inert, noncollageneous and nonantigenic.	**Yes**	**Yes**	**Identical**
Suture is dyed with D&C Violet #2 with content below 0.1 wt% being monofilament it is coated.	**Yes**	**Yes**	**Identical**
Offered in a variety of lengths and a range of diameters with or without various needles attached.	**Yes**	**Yes**	**Identical**
Suture is supplied for single use only	**Yes**	**Yes**	**Identical**
Suture is sterilized by EtO gas	**Yes**	**Yes**	**Identical**
Suture is packaged in the same or equivalent manner, and has the same equivalent labeling claims as that of the predicate device(s) including indications, warnings, cautions and precautions	**Yes**	**Yes**	**Identical**
Meets are exceeds the performance requirements for “Absorbable Surgical Suture” as defined in the Official Monograph of the USP (exceptions diameter)	**Yes**	**Yes**	**Identical**
Meets the performance requirements defined in the USP for “Suture Length Requirement” 95% of stated label length	**Yes**	**Yes**	**Identical**

Meets the performance requirements defined in the USP current edition for sterility	**Yes**	**Yes**	**Identical**
Suture is biologically compatible when tested as per ISO 10993	**Yes**	**Yes**	**Identical**
Suture is tested and proved to be non-toxic when tested as per ISO 10993 for toxicity	**Yes**	**Yes**	**Identical**
Days Implantation	**Approximate % Original Strength Remaining**		
14 days	**70%**		**Identical**
28 days	**50%**		**Identical**
42 days	**25%**		**Identical**

Non Clinical Testing

Non-clinical laboratory testing was conducted to confirm that the REDIDIOX Suture conforms to USP monograph for absorbable sutures for tensile strength, diameter, needle attachment, extractable color, sterilization validation, shelf life, and biocompatibility. This testing was performed in accordance with FDA's Class II Special Controls Guidance Document: Surgical Sutures, Issued June 3, 2003, and Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, Issued May 1, 1995

Substantial Equivalence Conclusion

The REDIDIOX Suture is substantially equivalent to the predicate in Indications for Use, operating principle, device design and material. The results of safety and efficacy testing demonstrates that the REDIDIOX Suture is substantially equivalent to the predicate device and raises no new issues of safety and effectiveness.