MAR 2 6 2014

RIVERPOINT MEDICAL

K140415

510(k) Summary

Submitter Information

Submitter's Name:	Riverpoint Medical
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Registration Number:	3006981798
Contact Person:	Douglas Rowley (503) 517-8001
Date of Preparation:	February 11th, 2014

Device Name

Trade Name:	MonoTex
Common Name:	PTFE Nonabsorbable Surgical Sutures
Classification Name:	Suture, surgical, nonabsorbable, expanded Polytetrafluoroethylene

Device Classification

FDA Class:	2
Product Classification:	878.5035: Nonabsorbable expanded polytetrafluoroethelene surgical suture
Code:	NBY
Classification Panel:	Class II (special controls); General and Plastic Surgery

Predicate Devices (applicable 510(k) number listed):

K072076 (Cytoplast PTFE Suture, Osteogenics Biomedical, Inc.)

Special Controls

FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" was followed during the preparation of this submission.

Device Description

MonoTex Polytetrafluoroethylene (PTFE) nonabsorbable surgical sutures are medical devices used to secure tissues together or create wound closures during a surgical procedure or after an injury. MonoTex PTFE sutures are monofilament, and are composed of expanded polytetrafluoroethylene material attached to a standard medical grade suture needle as applicable (sutures can be provided without needles as well). Available Suture sizes will be standard according to USP requirements (6/0 through 5).

Intended Uses

Riverpoint MonoTex PTFE surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. MonoTex PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. MonoTex PTFE suture is provided sterile as a single use device.

Substantial Equivalence

MonoTex PTFE nonabsorbable sutures have been designed and manufactured to be substantially equivalent to the predicate device listed for safety and effectiveness. Materials used were selected based on known biocompatibility and established histories of use in the medical device industry for implantable devices, and are identical or substantially equivalent to the materials used in the predicate devices listed. MonoTex PTFE sutures have been designed to meet the requirements for diameter, tensile strength, and needle attachment strength as specified per USP unless stated otherwise on labeling. Testing is performed on each lot of product to verify that requirements have been met prior to release.

Technological Characteristics

The MonoTex PTFE sutures within this submission have substantially equivalent technological characteristics as the predicate device listed. As with the predicate device, MonoTex PTFE sutures are monofilament, uncoated, synthetic nonabsorbable surgical sutures. MonoTex PTFE sutures are provided sterile for one-time use only, and meet USP requirements unless stated otherwise within labeling.

Performance Data

Per FDA's *Special Control Guidance Document: Surgical Sutures*, performance testing, including mechanical testing in accordance to USP for nonabsorbable suture and biocompatibility testing of the suture material in accordance to ISO 10993-1 has been performed to further ensure substantial equivalence with the predicate devices listed. All testing performed has demonstrated that MonoTex PTFE sutures are as safe and effective as the predicate, will meet current performance requirements for nonabsorbable surgical sutures unless stated otherwise in labeling, and that they are substantially equivalent to the applicable predicate devices.

Conclusion

Based on the information provided within this 510(k) submission, Riverpoint Medical concludes that the proposed MonoTex PTFE sutures are substantially equivalent to the predicate devices listed according to the requirements of the Federal Food, Drug, and Cosmetic Act.

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 26, 2014

Riverpoint Medical
Mr. Douglas Rowley
825 Northeast 25th Avenue
Portland, Oregon 97232

Re: K140415
Trade/Device Name: MONOTEX PTFE Suture
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable expanded polytetrafluoroethylene surgical suture
Regulatory Class: Class II
Product Code: NBY
Dated: February 11, 2014
Received: February 18, 2014

Dear Mr. Rowley:

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 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. 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,

David Krause -S

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

Enclosure

RIVERPOINT MEDICAL

K140415

Indications for Use Statement

510(k) Number: Unknown at this time

Device Name: Nonabsorbable expanded polytetrafluoroethylene (PTFE) surgical suture

Trade Name: MonoTex

Indications for Use:

MonoTex PTFE surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. MonoTex PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues.
MonoTex PTFE suture is provided sterile as a single use device.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter L. Hudson -S
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