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

February 12, 2016

Riverpoint Medical
Mr. Edwin Anderson
Director of Quality and Regulatory
825 NE 25th Avenue
Portland, Oregon 97232

Re: K153307
Trade/Device Name: HS SutureTape
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable, polyethylene terephthalate surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: January 13, 2016
Received: January 14, 2016

Dear Mr. Anderson:

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" (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 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 yours,

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)*
K153307

Device Name
HS SutureTape®

Indications for Use *(Describe)*
HS Fiber® Suture is intended to be used in general soft tissue approximation and/or ligation, including use in cardiovascular, and the use of allograft tissue for orthopedic procedures.

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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RIVERPOINT MEDICAL

510(k) SUMMARY

Riverpoint Medical HS SutureTape® Line Extension

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or 866 445-4923
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Edwin Anderson (503) 517-8001
Date of Preparation:	November 13th, 2015

Device Name

Trade Name:	HS SutureTape®
Common or Usual Names:	Polyblend Suture, Non-absorbable Surgical Sutures
Classification Name:	Nonabsorbable poly(ethylene terephthalate) Surgical Suture

Device Classification

FDA Class:	II
Product Classification:	878.5000: Suture, nonabsorbable, synthetic, polyethylene
Classification Code:	GAT
Review Panel	General & Plastic Surgery
Premarket Review	Office of Device Evaluation Division of Surgical Devices, Plastic and Reconstructive General Surgery Devices Branch

Predicate Device

K100006 – Riverpoint Medical HS Fiber (Polyblend)

Device Description

The Riverpoint Medical HS Fiber® sutures are non-absorbable, sterile, surgical sutures composed of multiple single strands of ultra-high molecular weight polyethylene (UHMWPE) braided together to form the implant. HS Fiber sutures are available in common sizes and lengths with or without pre-attached needles. HS SutureTape is a flat braid configuration of the HS Fiber suture.

Intended Use / Indications for Use

HS Fiber® Suture is intended to be used in general soft tissue approximation and/or ligation, including use in cardiovascular, and the use of allograft tissue for orthopedic procedures.

Performance Data

The Riverpoint Medical HS Fiber Sutures meet requirements established by the United States Pharmacopeia. The HS Fiber sutures are tested per USP performance requirements for needle attachment and tensile strength. FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" was followed during the preparation of this submission. Materials used were evaluated per ISO 10993-1:2009 – Biological Evaluation of Medical Devices. Limulus Amebocyte Lysate (LAL) endotoxin quantification assessments, both process validation and routine testing, demonstrate endotoxin quantities below the recommended limits outlined in FDA Guidance "Pryogens and Endotoxins Testing: Questions and Answers." Rabbit pyrogenicity assessments were also performed on a manufacturing process-validation basis with periodic determinations.

Substantial Equivalence and Comparison of Technical Characteristics

The HS SutureTape line extension is substantially equivalent to the previously cleared HS Fiber Sutures. The HS SutureTape has the same intended use and indications for use, the same principles of operation, and similar technical characteristics as the predicate device. Both the HS SutureTape and the predicate device are sterilized using the same processes, are composed of the same material, and are tested per USP performance requirements for tensile strength, needle and attachment. The minor difference in technical characteristics is limited to the braiding configuration, and the line extension introduces a braiding configuration differing from the originally cleared device. These differences do not raise new questions of safety or effectiveness, therefore the HS SutureTape line extension is substantially equivalent to the currently marketed predicate device.

Conclusion

The information provided in this Special 510(k) demonstrates that the Riverpoint Medical HS SutureTape line extension is substantially equivalent to the predicate device.