



September 10, 2020

Riverpoint Medical, LLC
Edwin Anderson
VP of Regulatory Affairs and Quality Assurance
825 NE 25th Ave
Portland, Oregon 97232

Re: K202242

Trade/Device Name: HS Fiber

Regulation Number: 21 CFR 878.5000

Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture

Regulatory Class: Class II

Product Code: GAT

Dated: August 7, 2020

Received: August 10, 2020

Dear Edwin 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K202242

Device Name
HS Fiber

Indications for Use (Describe)

HS Fiber sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular surgery, and the use of allograft tissues 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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510(k) SUMMARY**Riverpoint Medical HS Fiber® Suture 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: August 7, 2020

Device Name

Trade Name: HS Fiber® Suture

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.

Intended Use / Indications for Use

HS Fiber sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular surgery, and the use of allograft tissues 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 10993-1:2018 – 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 “Pyrogens and Endotoxins Testing: Questions and Answers.”

Substantial Equivalence and Comparison of Technical Characteristics

The HS Fiber stiffened suture long line extension is substantially equivalent to the previously cleared HS Fiber Sutures. The HS Fiber suture line extension has the same intended use and indications for use, the same principles of operation, and similar technical characteristics as the predicate device, HS Fiber suture cleared per K100006. Both the HS Fiber suture line extension and the predicate device are sterilized using the same processes, are composed of the same material (UHMWPE), and are tested per USP performance requirements for length, tensile strength and needle attachment. The minor differences do not raise new questions of safety or effectiveness; therefore, the HS Fiber suture 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 Fiber suture line extension is substantially equivalent to the predicate device.