July 26, 2023

Riverpoint Medical, LLC
Edwin Anderson
VP of Regulatory Affairs
815 NE 25th Ave
Portland, Oregon 97232

Re: K220765
Trade/Device Name: HS Fiber® Cerclage
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ, GAT
Dated: July 13, 2023
Received: July 14, 2023

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220765

Device Name
HS Fiber® Cerclage

Indications for Use *(Describe)*
HS Fiber Cerclage sutures are indicated for use in general soft tissue approximation and/or ligation. These sutures may be used in cardiovascular surgeries, and orthopedic surgeries using allograft or autograft tissue. When used as a bone fixation cerclage, the sutures are intended for:
• Trauma surgery indications including olecranon, ankle, patella, and some shoulder rewiring.
• Repair of long bone fracture due to trauma or reconstruction.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Riverpoint Medical HS Fiber® Cerclage

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Becca DeFrancia (503) 517-8001
Date of Preparation:	July 13, 2023

Device Name

Trade Name:	HS Fiber® Cerclage
Common or Usual Names:	Bone Fixation Cerclage, Suture
Classification Name:	21 CFR 888.3010: Bone Fixation Cerclage 21 CFR 878.5000: Nonabsorbable Poly(ethylene) Terephthalate Surgical Suture

Device Classification

FDA Class:	II
Product Classification:	888.3010, 878.5000
Classification Code:	JDQ, GAT

Predicate Device(s)

K170206 (Primary) – Arthrex FiberTape Cerclage

K100006 (Reference) – Riverpoint Medical HS Fiber (Polyblend)

Device Description

The Riverpoint Medical HS Fiber® Cerclage 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 Cerclage sutures are available in common sizes and lengths with or without pre-attached needles. Suture supplied meet United States Pharmacopeia (USP) requirements for non-absorbable suture except for diameter. The device is sterilized by ethylene oxide gas, and is provided sterile for single use. The device is intended for use in a hospital/clinic/surgical setting.

The classification for the HS Fiber Cerclage is FDA Class II device with product classification 21 CFR §878.5000, Product Code GAT and subsequent 21 CFR §888.3010, Product Code JDQ.

Indications for Use:

HS Fiber Cerclage sutures are indicated for use in general soft tissue approximation and/or ligation. These sutures may be used in cardiovascular surgeries, and orthopedic surgeries using allograft or autograft tissue. When used as a bone fixation cerclage, the sutures are intended for:

- Trauma surgery indications including olecranon, ankle, patella, and some shoulder rewiring.
- Repair of long bone fracture due to trauma or reconstruction.

Performance Data

The sutures used to construct the HS Fiber Cerclage meet requirements established by the United States Pharmacopeia (USP), except for diameter. The UHMWPE 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" were followed during the preparation of this submission.
Non-clinical performance testing for the Riverpoint Medical HS Fiber Cerclage included sterilization validation per EN ISO14937:2009 - *Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*, biocompatibility testing per ISO10993-1:2018 - *Biological Evaluation of Medical Devices,* stability testing on the product and packaging per ISO 11607-1:2019 - Packaging for terminally sterilized medical devices -- Part 1: *Requirements for materials, sterile barrier systems and packaging systems,* and a simulated use Usability Validation performed per EN62366-1: 2015- Medical devices - *Application of usability engineering to medical devices*. All acceptance criteria were met, and the Riverpoint Medical HS Fiber Cerclage Suture performed as intended. Non-clinical mechanical testing was performed to verify the fixation performance for the HS Fiber Cerclage using tensile strength, knot strength, fatigue strength, creep, and wear debris with particle analysis. Results of the performance testing for the HS Fiber Cerclage device concluded that the device performed comparably to the predicate device in tensile strength, knot strength, fatigue strength, creep, and wear debris. The tests performed demonstrated that the HS Fiber Cerclage met all requirements for its intended use.