August 13, 2025

Riverpoint Medical
Paul Vagts
Sr. Regulatory Associate III
825 NE 25th Ave
Portland, Oregon 97232

Re: K252201
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: July 14, 2025
Received: July 14, 2025

Dear Paul Vagts:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252201

Device Name
HS Fiber®

Indications for Use *(Describe)*
The Riverpoint Medical HS Fiber® sutures are indicated for injury and/or reconstruction of soft tissue, excluding the ones listed in contraindications, where soft tissue ligation or approximation is required. The Riverpoint Medical HS Fiber® sutures are also indicated for conditions where allograft tissues are required to be fixated, such as ACL tears.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY-K252201
Riverpoint Medical HS Fiber® Suture

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:	Paul Vagts (503) 517-8001
Date of Preparation:	13Aug2025

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

K231163 – Riverpoint Medical HS Fiber Sutures

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

The Riverpoint Medical HS Fiber® sutures are indicated for injury and/or reconstruction of soft tissue, excluding the ones listed in contraindications, where soft tissue ligation or approximation is required. The Riverpoint Medical HS Fiber® sutures are also indicated for conditions where allograft tissues are required to be fixated, such as ACL tears.

Substantial Equivalence and Comparison of Technical Characteristics

The HS Fiber suture is technologically identical to the predicate device. The HS Fiber suture has the same intended use, the indications for use statement only slightly differs in wording, the same principles of operation, and the same technical characteristics as the predicate device, HS Fiber suture cleared per K231163. No changes are being proposed to how the devices are sterilized, the processes used for manufacturing, the materials from which the devices are composed (UHMWPE), or finished goods testing which is done per USP performance requirements for length, tensile strength and needle attachment. The minor difference between the devices is limited to the labeling of the device. The update to the labeling is limited to a slight modification of the Indication for Use statement and the addition of several contraindications outside of the scope of the cleared indications. This difference does not raise new questions of safety or effectiveness; therefore, this HS Fiber suture update is substantially equivalent to the currently marketed predicate device.

Performance Data

The updates being proposed are limited to the labeling, no additional performance testing or biological evaluation was required.

Conclusion

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