January 05, 2024

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

Re: K231163
Trade/Device Name: HS Fiber Sutures
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: November 15, 2023
Received: November 15, 2023

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.

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

Digitally signed by Tek N. Lamichhane -S
Date: 2024.01.05 22:48:06 -05'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
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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.

Submission Number *(if known)*

K231163

Device Name

HS Fiber Sutures

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.

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.

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510(k) SUMMARY
K231163 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:	05Jan2024

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

Predicate Device

K190817 – HS Fiber Suture

Reference Device

K222500 – AIR OPTIX® COLORS

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 surgeries.

Substantial Equivalence and Comparison of Technical Characteristics

The HS Fiber suture line extension is substantially equivalent to the previously cleared HS Fiber Sutures and Suture Tapes. 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 K190817. 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.

Device	**HS Fiber Suture (Proposed Device, K231163)**	**HS Fiber Suture (Predicate Device, K190817)**	**Comparison**
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.	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.	Identical
Material	UHMWPE	UHMWPE	Identical
Regulation Number	878.5000	878.5000	Identical
Regulatory Class	II	II	Identical
Prescription or OTC	Prescription	Prescription	Identical
Product Code	GAT	GAT	Identical
Color Additive Regulation	21CFR74 and 21CFR73	21CFR74 and 21CFR73	Identical
Braid Shape	Round Braid, Flat Braid	Round Braid, Flat Braid	Identical
Braid Size	6/0 through 7; 1mm-5mm width	6/0 through 7; 1mm-5mm width	Identical
Needles	300 or 400 Stainless Steel	300 or 400 Stainless Steel	Identical
Packaging	Tyvek/Poly Pouch	Tyvek/Poly Pouch	Identical
Biocompatibility	Biocompatible per ISO 10993	Biocompatible per ISO 10993	Identical
Sterilization	EtO Sterilization	EtO Sterilization	Identical

The minor difference between the devices is limited to the color additive. While this color additive is new to HS Fiber, it has a long history of use with contact lenses as demonstrated by reference device cleared per K222500. This difference does not raise new questions of safety or effectiveness; therefore, the HS Fiber suture line extension is substantially equivalent to the currently marketed predicate device.

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 “Pryogens and Endotoxins Testing: Questions and Answers.”

Conclusion

The information provided in this Traditional 510(k) demonstrates that the HS Fiber suture (K231163) is substantially equivalent to the predicate device (K190817 – HS Fiber Suture).