November 26, 2024

Riverpoint Medical LLC
Paul Vagts
Regulatory Affairs Manager
825 NE 25th Ave.
Portland, Oregon 97232

Re: K242494
Trade/Device Name: OsseoFit Interfacing Anchor; OsseoFit Bone Tunnel Construct
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, GAT
Dated: October 28, 2024
Received: October 28, 2024

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242494

Device Name

OsseoFit Interfacing Anchor;
OsseoFit Bone Tunnel Construct

Indications for Use *(Describe)*

The OsseoFit Interfacing Anchor and OsseoFit Bone Tunnel Construct are intended for use in soft tissue to bone fixation for the following indications:
Shoulder Rotator Cuff Repair

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
OsseoFit Interfacing Anchor and OsseoFit Bone Tunnel Construct
K242494

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or (971) 288-1083 (503) 517-8002
Fax Number:	3006981798
Registration Number:	
Contact Person:	Paul Vagts
	(503) 517-8001
Date of Preparation:	October 27th, 2024

Device Name

Trade Name:	OsseoFit Interfacing Anchor; OsseoFit Bone Tunnel Construct
Common or Usual Names:	Fastener, Fixation, Nondegradable, Soft Tissue

Primary Device Classification

Product Code:	MBI
FDA Class:	2
Regulation Number:	888.3040: Smooth or threaded metallic bone fixation fastener

Secondary Device Classification

Product Code:	GAT
FDA Class:	2
Regulation Number:	878.5000: Suture, Non-absorbable, Synthetic, Polyethylene

Predicate Device

K203740 – Riverpoint Medical JuggerKnot Soft Anchor

Device Description

The Riverpoint Medical Interfacing Anchor is comprised of a pre-deployed all-suture anchor with attached repair sutures and 302 stainless steel needles. The Interfacing Anchor is inserted into either the humerus or into passing slots available in devices intended for total shoulder arthroplasty. The Riverpoint Medical Bone Tunnel Construct is comprised of a double armed Ultra-High Molecular Weight Polyethylene (UHMWPE) suture with a preassembled polypropylene passing loop and 302 stainless steel

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needles. The Bone Tunnel Construct is passed through the passing slots available in devices intended for total shoulder arthroplasty.

Suture supplied meet United States Pharmacopeia (USP) requirements for non-absorbable suture except for diameter. Suture dyes are FDA authorized. The device is sterilized by ethylene oxide gas and is provided sterile for single use. Interfacing Anchor and Bone Tunnel Construct are available in common sizes and lengths with pre-attached 302 stainless steel needles and will be sold sterile for single use. The device is intended for use in a hospital/clinic/surgical setting.

Intended Use / Indications for Use

The OsseoFit Interfacing Anchor and OsseoFit Bone Tunnel Construct are intended for use in soft tissue to bone fixation for the following indications:

Shoulder Rotator Cuff Repair

Performance Data

The sutures used to construct the OsseoFit Interfacing Anchor and OsseoFit Bone Tunnel Construct 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 “Bone Anchors - Premarket Notification (510(k)) Submissions Guidance for Industry and Food and Drug Administration Staff” and 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 Soft Anchor and Bone Tunnel Construct included a usability engineering validation with simulated use in a cadaveric models performed per EN62366: 2015- Medical devices - Application of usability engineering to medical devices. Endotoxin/pyrogenicity testing was performed per ANSI/AAMI ST72:2019, USP <161>, USP <151> and USP <85>. 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.” Non-clinical mechanical testing was performed to verify the fixation strength of the Soft Anchor and Bone Tunnel Construct and is compared to the predicate device.

In all instances of the testing referenced above, the acceptance criteria were met, and the proposed OsseoFit Interfacing Anchor and OsseoFit Bone Tunnel Construct performed as intended. Results of performance testing for the OsseoFit Interfacing Anchor and OsseoFit Bone Tunnel Construct concluded that the device performed comparably to the predicate device in cyclic and pullout testing and the validations performed demonstrated that the OsseoFit Interfacing Anchor and OsseoFit Bone Tunnel Construct met all requirements for its intended use.

Comparison of Technical Characteristics

The main difference in technical characteristics of the existing JuggerKnot Soft Anchor is that the proposed OsseoFit Interfacing Anchor and OsseoFit Bone Tunnel Construct is anchor configuration, instructions for use including fixation through passing slots available in devices intended for total shoulder arthroplasty, and principles of operation.

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The JuggerKnot Soft Anchor predicate device is sterilized using the same processes, packaged using the same packaging materials, composed of the same materials, and tested to comparable performance requirements. The minor differences in technical characteristics are limited to 1) Anchor geometry, 2) Principles of Operation, and 3) Instructions for Use.

However, Riverpoint Medical believes these minor differences do not raise any new questions of safety or effectiveness. A usability engineering study was performed to evaluate the performance of the proposed OsseoFit Interfacing Anchor and OsseoFit Bone Tunnel Construct device. In addition, bench testing was performed under simulated clinical conditions in order to evaluate the intended use listed in the IFU. Results of the usability study and performance testing of the OsseoFit Interfacing Anchor and OsseoFit Bone Tunnel Construct support the use of the device and applicable IFU.

Substantial Equivalence

The OsseoFit Interfacing Anchor and OsseoFit Bone Tunnel Construct has similar intended use and indications for use and similar technical characteristics as the predicate device. The information provided in this Traditional 510(k) demonstrates the (1) any differences in technological characteristics of the predicates do not raise any new questions of safety and efficacy and (2) the proposed device is at least as safe and effective as the predicate devices. Therefore, the Riverpoint Medical OsseoFit Interfacing Anchor and OsseoFit Bone Tunnel Construct is substantially equivalent to the predicate device.