August 19, 2024

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

Re: K241282
Trade/Device Name: RibFix Titan™ Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HTN
Dated: May 16, 2024
Received: July 19, 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.

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
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)*

K241282

Device Name

RibFix Titan™ Fixation System

Indications for Use *(Describe)*

The RibFix Titan Fixation System is indicated for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic bone.

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
RibFix Titan Fixation System
K241282

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or (971) 288-1083
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Paul Vagts (503) 517-8001
Date of Preparation:	August 19th, 2024

Device Name

Trade Name:	RibFix Titan Fixation System
Common or Usual Names:	Thoracic fixation system

Primary Device Classification

Product Code:	HRS
FDA Class:	2
Regulation Number:	888.3030: Single/multiple component metallic bone fixation appliances and accessories

Additional Device Classification

Product Code:	HTN
FDA Class:	2
Regulation Number:	888.3030: Single/multiple component metallic bone fixation appliances and accessories

Primary Predicate Device

K203474 – Biomet Microfixation RibFix Advantage System

Additional Predicate Device

K212608 – RibFix Blu Thoracic Fixation System

Reference Devices

K203740 – JuggerKnot Soft Anchor

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Device Description

The Riverpoint Medical RibFix Titan Fixation System is comprised of titanium bone plates that are secured to bone by a deployable ultra-high molecular weight polyethylene (UHMWPE) suture anchor with a titanium washer and button. Bone plates are provided in configurations for intrathoracic and extrathoracic use. Intrathoracic bone plates are provided in 60mm and 94mm lengths. Extrathoracic bone plates are provided in 60mm, 94mm, and 120mm lengths.

Intended Use / Indications for Use

The RibFix Titan Fixation System is indicated for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic bone.

Performance Data

Non-clinical mechanical testing was performed to verify the fixation strength of the RibFix Titan Fixation System and is compared to the predicate device. Testing conducted includes the following:

- Four-point bend testing (static and fatigue) of bone plate components per ASTM F382 Standard Specification and Test Method for Metallic Bone Plates.
- Cyclic and Ultimate Tensile Strength (UTS) testing of anchor constructs.
- Cyclic fatigue testing of assembled constructs using ASTM F1717 as a guide.
- Usability engineering validation with simulated use in cadaver lab performed per EN62366-1.
- MR Compatibility testing per ASTM F2052, ASTM F2213, ASTM F2119, ASTM F2182.

In all instances of the testing referenced above, the acceptance criteria were met, and the proposed RibFix Titan Fixation System performed as intended.

Comparison of Technical Characteristics

The main difference in technical characteristics of the existing RibFix devices is that the proposed RibFix Titan uses suture for fixation of fracture plate to bone whereas the existing devices use screws or threaded rods. The design of the RibFix Titan bone plates is similar to that of the predicate device.

The RibFix Titan and the JuggerKnot Soft Anchor reference device are sterilized using the same processes, are composed of the same materials, and are tested per comparable performance requirements. The minor differences in technical characteristics between the RibFix Titan and predicate RibFix devices are limited to:

1) the subject device is provided with the adjustable suture anchor to attach the bone plate to rib whereas the predicate RibFix devices use bone screws or threaded rods, and

2) the subject device can be used intrathoracically or extrathoracically whereas the predicate RibFix Advantage System can only be used intrathoracically, and the predicate RibFix Blu System can only be used extrathoracically.

However, Riverpoint Medical believes these minor differences do not raise any new questions of safety or effectiveness and they were designed to provide better versatility with an improved/simplified user interface. A usability engineering study was performed to evaluate the performance of the proposed RibFix Titan device. In addition, bench testing was performed under simulated clinical conditions in order to evaluate the intended use listed in the eIFU for worst case RibFix Titan product configurations. Results of the usability study and performance testing of the RibFix Titan support the use of the RibFix Titan Fixation System and eIFU.

Substantial Equivalence

The RibFix Titan Fixation System has the same intended use and indications for use, similar principles of operation, 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 effectiveness and (2) the proposed device is at least as safe and as effective as the predicate and reference devices. Therefore, the Riverpoint Medical RibFix Titan Fixation System is substantially equivalent to the predicate device.