March 20, 2025

Riverpoint Medical LLC
Edwin Anderson
Official Correspondent
825 NE 25th Ave
Portland, Oregon 97272

Re: K243988
Trade/Device Name: RootMend MRR
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, HTN
Dated: December 23, 2024
Received: December 26, 2024

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 (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, M.S.
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)*

K243988

Device Name

RootMend MRR

Indications for Use *(Describe)*

The RootMend MRR devices are intended to be used for suture (soft tissue) fixation to bone in the knee for meniscal root 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.

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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RP RIVERPOINT

510(k) SUMMARY
RootMend Meniscal Root Repair (MRR) Devices

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:	Edwin Anderson (503) 517-8001
Date of Preparation:	December 23rd, 2024

Device Name

Trade Name:	RootMend MRR
Common or Usual Names:	Fastener, fixation, nondegradable, soft tissue

Primary Device Classification

Product Codes:	MBI, HTN
FDA Class:	2
Regulation Number:	888.3040: Smooth or threaded metallic bone fixation fastener.

Predicate Device

K203495 – Arthrex SwiveLock Anchor

Reference Device

K230212 – OrthoButton AL

Device Description

The RootMend Meniscal Root Repair (MRR) devices are composed of uncoated UHMWPE (ultra-high molecular weight polyethylene) with UHMWPE tracer material. RootMend MRR devices are available with a fixation button composed of a titanium (Ti-6Al-4V) button, or with an attached UHMWPE fixation button. RootMend MRR devices will be provided sterile using ethylene oxide, for single use only, and are not to be re-sterilized. The UHMWPE is available undyed (white), black, or blue, with trace filaments of black or blue. RootMend MRR devices are intended to be used for suture (soft tissue) fixation to bone in the knee for meniscal root repair.

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Intended Use / Indications for Use

The RootMend MRR devices are intended to be used for suture (soft tissue) fixation to bone in the knee for meniscal root repair.

Performance Data

Non-clinical mechanical testing was performed to verify the fixation strength of the RootMend MRR devices and is compared to the predicate device. Testing conducted includes cyclic and ultimate tensile strength (UTS) testing, and assessment of displacement for the subject button and predicate anchor constructs. Usability engineering testing with simulated use in cadaver lab was performed on the subject device per EN62366-1. In all instances of the testing referenced above, the acceptance criteria were met, and the proposed RootMend MRR devices performed as intended.

Additional non-clinical testing for the RootMend MRR materials and packaging included sterilization validation per ISO 14937:2009 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 including biocompatibility ISO 10993-7:2008 for Biological evaluation of medical devices-Part 7 Ethylene Oxide Sterilization Residuals, biocompatibility testing per ISO10993-1:2009 - Biological Evaluation of Medical Devices, stability testing on the product material and packaging per ISO 11607-1:2006 - Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems. LAL and rabbit pyrogenicity testing has demonstrated that the materials used in the RootMend MRR devices do not raise any additional concerns.

Substantial Equivalence and Comparison of Technical Characteristics

The proposed RootMend MRR device is within the scope of the intended use and indications, has similar principles of operation, and has similar technical characteristics as the predicate Arthrex SwiveLock (K203495) and reference OrthoButton AL (K230212). The minor technical differences are that the subject device is provided with an adjustable loop and a titanium or all-suture soft button for fixation to the bone instead of using an anchor body. These minor differences are within the range of currently marketed devices (K203495, K230212, K160655, K223284), and therefore, do not raise any issues of safety or effectiveness.

Conclusion

The information provided in this Traditional 510(k) demonstrated that the RootMend MRR subject device is substantially equivalent to the predicate.