March 11, 2026

Riverpoint Medical, LLC
Palmira Obeso
Regulatory Associate II
825 NE 25th Ave.
Portland, Oregon 97272

Re: K253693
Trade/Device Name: Strut Suture; No-Tie Button
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 9, 2026
Received: February 9, 2026

Dear Palmira Obeso:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253693

Please provide the device trade name(s).

Strut Suture;
No-Tie Button

Please provide your Indications for Use below.

Strut Suture:
The Strut Suture is intended to be used for fixation of bone to bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in ACL/PCL Repair.

No-Tie Button
The No-Tie Button is intended to be used for fixation of bone to bone, intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in ACL/PCL Repair when used with Strut Suture (or equivalent) and soft tissue fixation to bone in the knee for meniscal root repair when used with RootMend MRR (or equivalent).

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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K253693
510(k) SUMMARY
Strut Suture, No-Tie Button

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:	Palmira Obeso (503) 517-8001
Date of Preparation:	November 21st, 2025

Device Name

Trade Name:	Strut Suture; No-Tie Button
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.

Predicate Device

K202581 – Arthrex Tight Rope II

Reference Devices

K230212 – OrthoButton AL

K243988 – RootMend MRR

Device Description

Strut Suture devices are a suture and button construct composed of uncoated UHMWPE (ultra-high molecular weight polyethylene) with UHMWPE tracer material and an attachable fixation anchor composed of a titanium (Ti-6Al-4V) button. Strut Suture devices will be provided sterile using ethylene oxide, for single use only, and are not to be re-sterilized.

No-Tie Button devices are an attachable fixation anchor composed of a titanium (Ti-6Al-4V) button. No-Tie Button devices will be provided sterile using ethylene oxide, for single use only, and are not to be re-sterilized.

Intended Use / Indications for Use

The Strut Suture is intended to be used for fixation of bone to bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in ACL/PCL Repair.

The No-Tie Button is intended to be used for fixation of bone to bone, intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in ACL/PCL Repair when used with Strut Suture (or equivalent) and soft tissue fixation to bone in the knee for meniscal root repair when used with RootMend MRR (or equivalent).

Performance Data

Non-clinical mechanical testing was performed to verify the fixation strength of the Strut Suture and No-Tie Button devices and is compared to the predicate device. Testing conducted includes cyclic and UTS testing of anchor constructs and usability engineering testing with simulated use in cadaver lab performed per EN62366-1. In all instances of the testing referenced above, the acceptance criteria were met, and the proposed devices performed as intended.

Additional non-clinical testing for the Strut Suture and No-Tie Button 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 ISO 10993-1:2009 - 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 have demonstrated that the materials used in the Strut Suture devices are non-pyrogenic and do not raise any additional concerns.

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Substantial Equivalence and Comparison of Technical Characteristics

The proposed Strut Suture and No-Tie Button devices are within the scope of the intended use and indications, has similar principles of operation, and has similar technical characteristics as the predicate Arthrex Tight Rope II (K151342) and references OrthoButton AL (K230212) and RootMend MRR (K243988) No notable technical differences were identified. Therefore, the subject devices do not raise any issues of safety or effectiveness.

Conclusion

The information provided in this Traditional 510(k) demonstrates that the Strut Suture and No-Tie Button subject devices are substantially equivalent to the predicate device.