May 29, 2024

Arthrex, Inc.
Kristi Frisch
Regulatory Affairs Specialist, Principal
1370 Creekside Blvd
Naples, Florida 34108

Re: K241235
Trade/Device Name: Arthrex TightRope II
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 30, 2024
Received: May 2, 2024

Dear Kristi Frisch:

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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2024.05.29 10:45:47 -04'00'

Jesse Muir, Ph.D.
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)*

K241235

Device Name

Arthrex TightRope II

Indications for Use *(Describe)*

The Arthrex TightRope II devices are intended to be used for fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering these devices for ACL/ PCL repair and reconstruction for the adult and pediatric patient population; MCL, POL, LCL repair and reconstruction; IBT and PRT repair; and MPFL, ALL, quadriceps tendon, PLC repair and reconstruction.

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

Date Prepared	April 30, 2024
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Kristi Frisch Title: Regulatory Affairs, Principal Phone: 1-239-598-4302, ext. 73849 Email: Kristi.Frisch@Arthrex.com
Trade Name	Arthrex TightRope II
Common Name	Smooth or threaded metallic bone fixation fastener
Product Code	MBI – Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fastener
Regulatory Class	II
Primary Predicate Device	K231857 Arthrex TightRope II
Reference Devices	K221128 Arthrex TightRope II K202581 Arthrex TightRope II K232973 Arthrex FiberTak Suture Anchor K232742 Arthrex FiberTak Suture Anchor K231113 Arthrex FiberTak Suture Anchor
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to expand the device indications of the Arthrex TightRope II devices previously cleared under K231857, K202581 and K221128 to include: 1. Medial Patellofemoral Ligament (MPFL) repair and reconstruction 2. Anterolateral Ligament (ALL) repair and reconstruction 3. Quadriceps Tendon repair and reconstruction 4. Post-Lateral Corner (PLC) repair and reconstruction
Device Description	The proposed Arthrex TightRope II devices are comprised of a suture loop that may include passing sutures and/or metallic button. The suture loop and passing sutures are braided nonabsorbable surgical sutures. The button is made of titanium with hole s to

	permit suture passage and assembly with Arthrex sutures.
Indications for Use	The Arthrex TightRope II devices are intended to be used for fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering these devices for ACL/PCL repair and reconstruction for the adult and pediatric patient population; MCL, POL, LCL repair and reconstruction; IBT and PRT repair; and MPFL, ALL, Quadriceps Tendon, PLC repair and reconstruction.
Performance Data	Based on cyclic displacement/load displacement testing, the proposed Arthrex TightRope II device is equivalent to the Arthrex TightRope II device predicate device. This predicate equivalence supports the inclusion of the proposed indications for soft tissue repairs and reconstructions in the knee for the proposed Arthrex TightRope II devices.
Technological Comparison	The proposed Arthrex TightRope II devices have identical technological characteristics as the primary predicate and reference devices. The proposed Arthrex TightRope II devices are comprised of multiple sutures manufactured using the same materials as the reference device Arthrex FiberTak suture anchor.
Conclusion	Therefore, based on the intended use, fundamental scientific technology, and the data provided in this Special 510(k), Arthrex has determined that the proposed Arthrex TightRope II devices in this submission are substantially equivalent to the primary predicate device Arthrex TightRope II device and the reference device Arthrex FiberTak suture anchor.