October 5, 2022

Lai Saeteurn
Regulatory Affairs Specialist II
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K221128
Trade/Device Name: Arthrex ACL TightRope®, PCL TightRope®, and TightRope® II
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: April 14, 2022
Received: April 18, 2022

Dear Lai Saeteurn:

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 (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 located 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.

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 and Part 809; medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For:

Laura C. Rose, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221128

Device Name
Arthrex ACL TightRope®, PCL TightRope®, and TightRope® II

Indications for Use *(Describe)*
The Arthrex ACL TightRope®, PCL TightRope®, and 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared	October 5, 2022
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Lai Saeteurn Regulatory Affairs Specialist II 1-239-598-4302, ext. 71764 Lai.Saeteurn@Arthrex.com
Name of Device	Arthrex ACL TightRope®, PCL TightRope®, and TightRope® II
Common Name	Smooth or threaded metallic bone fixation fastener
Product Code	MAI – Single/Multiple component metallic bone fixation appliances and accessories MBI – Smooth or threaded metallic bone fixation fastener
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fastener 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	II
Predicate Device	K202581: Arthrex TightRope II K112990: ACL TightRope K110123: PCL TightRope
Reference Device	K130217: Orthopediatrics ACL Reconstructive System K201522: Arthrex Syndesmosis TightRope XP Buttress Plate Implant System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain pediatric indications for the Arthrex ACL TightRope®, PCL TightRope®, and TightRope® II devices cleared under K112990, K110123, and K202581.
Device Description	The Arthrex ACL TightRope®, PCL TightRope®, and 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 holes to permit suture passage and assembly with Arthrex sutures. The proposed devices are available in various device models referred to as TightRope® ABS, Implant; TightRope®, PCL; ACL TightRope® RT; ACL TightRope® II RT; ACL TightRope® II RT, Double Loaded Passing Sutures; BTB TightRope® II; BTB TightRope® II, Double Loaded Passing Sutures; and TightRope® II ABS, Implant Open.
Comparison Summary of Technological Characteristics and Modifications Proposed	The proposed devices have the same technological characteristics (device design, material, sterilization method, and biocompatibility profile). The proposed device modification is the addition of the pediatric patient population. The Arthrex ACL TightRope®, PCL TightRope®, and TightRope® II devices are substantially equivalent to the predicate device in which the design features and intended uses are the same. Any differences between the proposed device and the predicate devices are considered minor and do not result in new or different questions concerning safety or effectiveness.

Indications for Use	The Arthrex ACL TightRope®, PCL TightRope®, and 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.
Performance Data	Ultimate load testing and cyclic displacement was performed on the proposed devices and compared to the predicate device. The test results demonstrate that the proposed and predicate devices are equivalent. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Clinical Literature	Clinical literature was provided on the subject devices involving the proposed patient population of pediatric patients. The reviewed literature shows the device is effective when used in the proposed patient population.
Real World Data/Evidence	Real World Data/evidence is provided from the Surgical Outcomes System registry. Based on the patient outcomes, there are no statistical differences in patients less than 22 years of age versus patients greater than 22 years of age.
Conclusion	The Arthrex ACL TightRope®, PCL TightRope®, and TightRope® II devices are substantially equivalent to the predicate devices in which the basic design features and intended use are the same. Any differences between the proposed device and the predicate devices are considered minor and do not result in new or different questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex has determined that the proposed devices are substantially equivalent to the currently marketed predicate device.