December 22, 2025

Arthrex, Inc.
Stacy Valdez
Principal Regulatory Affairs Specialist
1370 Creekside Blvd.
Naples, Florida 34108

Re: K253727
Trade/Device Name: Syndesmosis TightRope PRO
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: November 24, 2025
Received: November 24, 2025

Dear Stacy Valdez:

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

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.	K253727

Please provide the device trade name(s).

Syndesmosis TightRope PRO

Please provide your Indications for Use below.

The Syndesmosis TightRope PRO is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Syndesmosis TightRope PRO is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

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

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Date Prepared	11/24/2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Stacy Valdez Title: Principal Regulatory Affairs Specialist Phone: 1-239-643-5553, ext. 72010 Email: stacy.valdez@arthrex.com
Trade Name	Syndesmosis TightRope PRO
Common Name	Washer, Bolt Nut
Product Code	HTN
Classification Name	21 CFR 888.3030: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class	II
Primary Predicate Device	K043248: Arthrex TightRope Syndesmosis Devices
Additional Predicate Devices	K201522: Arthrex Syndesmosis TightRope XP Buttress Plate Implant System
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance of the Syndesmosis TightRope PRO.
Device Description	The Syndesmosis TightRope PRO devices are comprised of various configurations of two metal buttons (round and oblong) preloaded onto an inserter with #5 suture (implanted) and #2-0 FiberWire suture (passing suture), a one-hole washer or two-hole buttress plate. The proposed Syndesmosis TightRope PRO devices will utilize the existing #5 suture (implanted) and two-hole buttress plate previously cleared within K201522 – Arthrex Syndesmosis TightRope XP Buttress Plate Implant System. The proposed Syndesmosis TightRope PRO devices may be packaged as standalone devices or together with ancillary instruments to aid in insertion.
Indications for Use	The Syndesmosis TightRope PRO is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Syndesmosis TightRope PRO is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.
Performance Data	To demonstrate product performance, Arthrex has conducted cyclic shear testing and ultimate shear testing on the proposed Syndesmosis TightRope Pro comparing the results to the

	acceptance criteria established and accepted by FDA in primary predicate device, Arthrex TightRope Syndesmosis TightRope Devices (K043248) and additional predicate device, Arthrex Syndesmosis TightRope XP Buttress Plate Implant System (K201522). MRI force, torque, and image artifact testing was previously conducted in accordance with FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, ASTM F2052 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*, ASTM F2119 *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*, ASTM F2182 *Standard Test Method for Measurement of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging* and ASTM F2213 *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*. Arthrex determined that the proposed Syndesmosis TightRope PRO does not represent a new worst-case in terms of MR compatibility and will be adopted into the MRI labeling previously reviewed and accepted by FDA within additional predicate device, Arthrex Syndesmosis TightRope XP Buttress Plate Implant System (K201522) and Arthrex ACL TightRope, PCL TightRope, and TightRope II (K221128). Assessment of the physical product attributes including product, design, size, and materials has determined that the Syndesmosis TightRope PRO does not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	Compared to the primary predicate device, Arthrex TightRope Syndesmosis Devices (K043248) and additional predicate device, Arthrex Syndesmosis TightRope XP Buttress Plate Implant System (K201522), the proposed Syndesmosis TightRope PRO has the same basic design features, intended use, fundamental scientific technology, materials, button configuration, dimensions, packaging configurations, MRI safety labeling, sterility, and shelf-life. The difference between the proposed Syndesmosis TightRope PRO and the primary predicate device, Arthrex TightRope Syndesmosis Devices (K043248) and additional predicate device, Arthrex Syndesmosis TightRope XP Buttress Plate Implant System (K201522) are as follows: • The proposed 2-Hole Oblong Button has a smaller width. • The proposed 4-Hole Round Button is thinner. • The proposed devices have a smaller drill bit diameter.

	• The proposed Syndesmosis TightRope PRO will include a new 1-Hole Button Extending Washer. • The proposed Syndesmosis TightRope PRO will be preassembled with a #2-0 FiberWire (passing suture). However, the #2-0 FiberWire is an existing suture braid previously cleared by FDA within Arthrex Suture Grafting Kit (K041554). Based on the intended use, fundamental scientific technology, and the data provided in this Special 510(k), Arthrex has determined that the proposed Syndesmosis TightRope PRO is substantially equivalent to the primary predicate device, Arthrex TightRope Syndesmosis Devices (K043248) and additional predicate device, Arthrex Syndesmosis TightRope Buttress Plate Implant System (K201522). Any differences between the proposed and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.
Conclusion	The Syndesmosis TightRope PRO is substantially equivalent to the predicate devices cleared under K043248 and K201522 in which the basic design features and intended use are the same. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate devices.