September 3, 2020

Arthrex Inc.
Rebecca R. Homan
Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108

Re: K201522
Trade/Device Name: Arthrex Syndesmosis TightRope XP Buttress Plate Implant System
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: June 4, 2020
Received: June 8, 2020

Dear Ms. Homan:

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); 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,

Laura C. Rose -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201522

Device Name

Arthrex Syndesmosis TightRope XP Buttress Plate Implant System

Indications for Use *(Describe)*

The Arthrex Syndesmosis TightRope XP Buttress Plate Implant System 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 Arthrex Syndesmosis TightRope XP Buttress Plate Implant System 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.

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	September 3, 2020
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Rebecca R. Homan Regulatory Affairs Specialist 1-239-643-5553, ext. 73429 rebecca.homan@arthrex.com
Name of Device	Arthrex Syndesmosis TightRope XP Buttress Plate Implant System
Common Name	Button/Suture
Product Code	HTN
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	II
Predicate Device	K043248: Arthrex TightRope Syndesmosis Devices
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Syndesmosis TightRope XP Buttress Plate Implant System.
Device Description	The Arthrex Syndesmosis TightRope XP Buttress Plate Implant System consists of one 2 Hole Syndesmosis Buttress Plate (titanium alloy), two Knotless TightRopes (titanium alloy buttons and UHMWPE braid suture) and various ancillary instruments to aid in insertion. The proposed Arthrex Buttress Plate is a metal plate is manufactured from either titanium alloy or stainless steel. The implantable devices are packaged with various ancillary instruments to aid in insertion. The implantable devices and various ancillary instruments are provided sterile and are single use.
Indications for Use	The Arthrex Syndesmosis TightRope XP Buttress Plate Implant System 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 Arthrex Syndesmosis TightRope XP Buttress Plate Implant System 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	Cyclic fatigue testing was conducted to demonstrate that the proposed Arthrex Syndesmosis TightRope XP Buttress Plate Implant System performs statistically equivalent to the predicate device cleared under K043248. MRI force, torque, and image artifact testing were 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*.

	Bacterial Endotoxins Test (BET) was performed on the Arthrex Syndesmosis TightRope XP Buttress Plate Implant System utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14. The testing conducted demonstrates that the Arthrex Syndesmosis TightRope XP Buttress Plate Implant System meets pyrogen limit specifications. Cytotoxicity, Sensitization, Irritation, Genotoxicity, Systemic Toxicity, Subchronic/Subacute Toxicity, Implantation and Material Characterization testing was conducted on the Arthrex Syndesmosis TightRope XP Buttress Plate Implant System in accordance with ISO 10993-1:2018. Assessment of physical product attributes including product, design, size, and materials as well as the conditions of manufacture and packaging has determined that the Arthrex Syndesmosis TightRope XP Buttress Plate Implant System does not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	The Arthrex Syndesmosis TightRope XP Buttress Plate Implant System is substantially equivalent to the predicate devices cleared under K043248 in which the basic design features, intended use, materials, fundamental scientific technology, indications for use, sterility and shelf-life are identical. The Arthrex Syndesmosis TightRope XP Buttress Plate Implant System contains a preloaded disposable inserter and an Arthrex Buttress Plate. The predicate devices cleared under K043248 did not contain a preloaded disposable inserter or an Arthrex Buttress Plate. The Arthrex Syndesmosis TightRope XP Buttress Plate Implant System has been evaluated for MR Conditional labeling; whereas the predicate devices cleared under K043248 were not evaluated for MR Conditional labeling. The Arthrex Syndesmosis TightRope XP Buttress Plate Implant System is a line extension to the predicate devices, which include minor dimensional modifications with no change to intended use or function. Any differences between the Arthrex Syndesmosis TightRope XP Buttress Plate Implant System and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex Syndesmosis TightRope XP Buttress Plate Implant System is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise different questions concerning safety or effectiveness. The submitted mechanical testing data demonstrates that the ultimate tensile strength and cyclic fatigue of the proposed device is substantially equivalent to that of the predicate device for the desired indications. 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 device.