June 6, 2022

Arthrex Inc.
Ivette Galmez
Regulatory Affairs Principal Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K220947
Trade/Device Name: Arthrex Knotless AC Repair Devices
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: March 30, 2022
Received: April 4, 2022

Dear Ivette Galmez:

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,

Limin Sun, Ph.D.
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*

K220947

Device Name

Arthrex Knotless AC Repair Devices

Indications for Use *(Describe)*

The Knotless AC Repair Devices are intended as adjuncts in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as adjuncts in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

The Knotless AC Repair Devices are intended to provide fixation during the healing process following syndesmotic trauma, such as fixation of acromioclavicular separation due to coracoclavicular ligament disruption.

The Knotless AC Repair Devices with distal clavicle plate button are intended for use with Arthrex clavicle plates for clavicle indications and may not be used alone.

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	May 26, 2022
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Ivette Galmez Regulatory Affairs Principal Specialist 1-239-643-5553, ext. 71263 Ivette.galmez@arthrex.com
Name of Device	Arthrex Knotless AC Repair Devices
Common Name	Suture Button
Product Code	HTN
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	II
Predicate Device	K052776: Arthrex TightRope Acromioclavicular (AC) Device
Reference Device	K112437: Arthrex Fracture System K143139: Arthrex Fracture System, Sterile K123341: Arthrex Pec Repair Button K202581: Arthrex TightRope II K112990: ACL TightRope
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Knotless AC Repair Devices as a line extension to the Arthrex TightRope AC Device cleared under K052776.
Device Description	The subject devices are suture constructs configured with one or two metal buttons made of titanium or stainless steel. The nonabsorbable suture is made of UHMWPE. Some of the subject devices are compatible with the Clavicle Fracture plates cleared under K112437.
Indications for Use	The Knotless AC Repair Devices are intended as adjuncts in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as adjuncts in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. The Knotless AC Repair Devices are intended to provide fixation during the healing process following syndesmotic trauma, such as fixation of acromioclavicular separation due to coracoclavicular ligament disruption. The Knotless AC Repair Devices with distal clavicle plate button are intended for use with Arthrex clavicle plates for clavicle indications and may not be used alone.
Summary of Technological Characteristics	The proposed devices have similar technological characteristics as the predicate. The subject devices are configured with two buttons and are made of the same materials as the predicate. Some models may include an attachable coracoid button. The subject devices are sold sterile for single use.
Performance Data	Ultimate load testing and cyclic displacement was performed on the subject device and compared to the predicate device to demonstrate that the modifications do not negatively impact mechanical strength. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications. 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, and ASTM F2182 Standard Test Method for Measurement of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging.

Conclusion	The Arthrex Knotless AC Repair Devices are substantially equivalent to the predicate in which the basic design features and intended use are the same. Any differences between the subject device and the predicate device are considered minor and do not raised questions concerning safety and effectiveness. 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.