May 2, 2022

Arthrex Inc.
Stacy Valdez
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K213837
Trade/Device Name: Arthrex Ankle Fracture System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: December 7, 2021
Received: December 9, 2021

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 (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,

Shumaya Ali, M.P.H.
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)*

K213837

Device Name

Arthrex Fracture Plates

Indications for Use *(Describe)*

The Arthrex Fracture Plates are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, fibula.

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:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213837

Device Name
Arthrex Low Profile Screws

Indications for Use *(Describe)*

The Arthrex Low Profile Screws (2.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates, and Osteotomy Plates.

The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.

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)

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510(k) Summary

Date Prepared	February 04, 2022
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Stacy Valdez Senior Regulatory Affairs Specialist 1-239-643-5553, ext. 72010 Stacy.valdez@arthrex.com
Name of Device	Arthrex Ankle Fracture System
Common Name	Plate, fixation, bone
Product Code	HRS (Primary) , HWC
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories (Primary) 21 CFR 888.3040: Smooth or threaded metallic bone fastener
Regulatory Class	II
Primary Predicate	K123241: Arthrex Fracture Plates
Reference Devices	K151732: Arthrex Fracture Plates K203294: Arthrex Pilon Fusion System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Ankle Fracture System.
Device Description	The proposed Arthrex Ankle Fracture System consists of a series of plates and screws of varying lengths and orientations for versatile treatment of distal tibia fractures. The Ankle Fracture System Plates consist of posterior and vertical plates that are anatomically contoured to provide fixation in the talus and may be available in left and right configurations. Each plate provides locking screw fixation. The proposed Arthrex Low Profile Screws are a family of fully threaded, solid, non-locking or locking screws; and partially threaded, cannulated and non-locking screws. The proposed plates and screws are manufactured from Titanium Alloy. The proposed plates and screws are sold sterile (Gamma) and non-sterile and are single-use.
Indications for Use	The Arthrex Fracture Plates are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, fibula. The Arthrex Low Profile Screws (2.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates, and Osteotomy Plates. The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.
Performance Data	Arthrex conducted Pull-out (ASTM F543-17), Failure Torque, Insertion Torque (ASTM F543-17) and 4-Point Bend (ASTM F382-17) testing to demonstrate that

	the Arthrex Ankle Fracture System performs statistically equivalent to the predicate devices cleared under K123241, K103705 and K143614. 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*. Arthrex Plates and Screws are tested for Bacterial Endotoxins Test (BET) 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 sterile devices within the Arthrex Plates and Screws meet pyrogen limit specifications. Assessment of physical product attributes including product, design, size, and materials has determined that the Arthrex Ankle Fracture System does not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	The Arthrex Ankle Fracture System is substantially equivalent to the predicate devices cleared under K123241 in which the basic design features, intended use, fundamental scientific technology, materials (screws only), shelf-life, and sterility are identical. The Arthrex Ankle Fracture System Plates are manufactured from Titanium Alloy Ti-6AL-4V conforming to ASTM F136. The primary predicate plates cleared under the Arthrex Fracture Plates, K123241 are manufactured from CP Grade 4 Titanium conforming to ASTM F67. The proposed Arthrex Ankle Fracture System plates are offered in widths ranging from 8 mm to 10/21.1 mm. The primary predicate plates cleared under the Arthrex Fracture Plates, K123241 are offered in widths ranging from 9 - 13/35 mm. The sterile Arthrex Ankle Fracture System Plates are packaged in a double Polyethylene/Tyvek pouch or a double Nylon/Nylon pouch. The non-sterile Arthrex Ankle Fracture System plates are packaged inside a Polyethylene Bag within an inner Zip-Lock Polyethylene Bag, a Double Polyethylene Bag, or a Single Polyethylene Bag. The primary predicate plates cleared under Arthrex Fracture Plates, K123241 are packaged in a polyethylene pouch. The sterile Arthrex Ankle Fracture System screws are packaged in a PETG Blister Tray with a Tyvek Lidding or a double Polyethylene/Tyvek pouch. The non-sterile Arthrex Ankle Fracture System screws are packaged inside a Polyethylene Bag within an inner Zip-Lock Polyethylene Bag or a Single Polyethylene Bag. The primary predicate screws cleared under Arthrex Fracture Plates, K123241 are packaged in a polyethylene pouch. The Arthrex Ankle Fracture System was evaluated for MR Conditional labeling as were the predicate devices cleared under K203294 and K210994.

	The Arthrex Ankle Fracture System is substantially equivalent to the predicate devices cleared under K123241, with minor modifications with no change to intended use or function. Any differences between the Arthrex Ankle Fracture System and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex Ankle Fracture System is substantially equivalent to the predicate devices cleared under K123241 in which the basic design features and intended use are the same. Any differences between the Arthrex Ankle Fracture System and the predicate devices are considered minor and do not raise different questions of safety or effectiveness. The submitted mechanical testing data demonstrates that the Pull-out, 4-Point Bend strength and Failure Torque/Insertion Torque of the Arthrex Ankle Fracture System is substantially equivalent to that of the predicate devices 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 devices.