October 3, 2022

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

Re: K222267
Trade/Device Name: Arthrex 2.4 mm Volar Distal Radius Plate 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: July 23, 2022
Received: July 28, 2022

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)*

K222267

Device Name

Arthrex 2.4 mm Volar Distal Radius Plate Sytem

Indications for Use *(Describe)*

The Arthrex 2.4 mm Volar Distal Radius Plate System is intended for internal fixation for fractures and reconstruction of the small bones, primarily including the distal radius and distal ulna. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and malunions. This system can be used for palmar, dorsal or orthogonal application.

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indications for Use

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

510(k) Number *(if known)*

K222267

Device Name

Arthrex Low Profile Screws

Indications for Use *(Describe)*

The Arthrex Low Profile Screws (2.4 mm, 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, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile, Small Fragment Plates, Distal Extremity Plates, and Distal Radius Plates.

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.

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510(k) Summary

Date Prepared	September 26, 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 2.4 mm Volar Distal Radius Plate System
Common Name	Plate, fixation, bone Screw, fixation, bone
Product Code	HRS, 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 fixation fastener
Regulatory Class	II
Predicate Device	K131474: Arthrex Distal Radius Plate System
Additional Predicate Device(s)	K150456: Arthrex Plates, Screws and Staples
Reference Device(s)	K203294: Arthrex Pilon Fusion System K213837: Arthrex Ankle Fracture System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex 2.4 mm Volar Distal Radius Plate System.
Device Description	The Arthrex 2.4 mm Volar Distal Radius Plate System consists of a series of plates and screws of varying lengths and orientations. The Arthrex 2.4 mm Volar Distal Radius Plates are 2.26 mm in thickness. Each plate provides locking screw fixation. The proposed plates are manufactured from CP Grade 4 Titanium conforming to ASTM F67. The plates are sold as sterile (Gamma), single-use, and non-sterile, single-use. The Arthrex Low Profile Screws are a family of fully threaded, solid, non-locking screws. The screw family is offered in 2.4 mm in diameter and range in lengths from 6 mm to 40 mm. The screws are manufactured from Titanium Alloy conforming to ASTM F136. The screws are sold sterile (Gamma) and are single-use.
Indications for Use	The Arthrex 2.4 mm Volar Distal Radius Plate System is intended for internal fixation for fractures and reconstruction of the small bones, primarily including the distal radius and distal ulna. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and mal-unions. This system can be used for palmar, dorsal, or orthogonal application. The Arthrex Low Profile Screws (2.4 mm 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, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile, Small Fragment Plates, Distal Extremity Plates, and Distal Radius Plates.
Performance Data	Arthrex conducted 4-Point Bend (ASTM F382-17) testing to demonstrate

	that the Arthrex 2.4 mm Volar Distal Radius Plate System plates perform statistically equivalent to the additional predicate devices cleared under Arthrex Plates, Screws and Staples, K150456. The devices cleared under the additional predicate Arthrex Plates, Screws and Staples, K150456 were originally cleared under primary predicate Arthrex Distal Radius Plate System, K131474. 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 2.4 mm Volar Distal Radius Plate 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 sterile devices within the Arthrex Plates meet pyrogen limit specifications.
Technological Comparison	The Arthrex 2.4 mm Volar Distal Radius Plate System is substantially equivalent to the predicate devices cleared under K131474 in which the basic design features, intended use, fundamental scientific technology, materials, shelf-life (non-sterile only), and sterility (non-sterile only) are identical. The Arthrex 2.4 mm Volar Distal Radius Plates are manufactured from CP Grade 4 Titanium conforming to ASTM F67 which is equivalent to the primary predicate Arthrex Distal Radius Plate System, K131474. The Arthrex 2.4 mm Volar Distal Radius Plates are 2.26 mm in thickness which is equivalent to the primary predicate Arthrex Distal Radius Plate System. The Arthrex Low Profile Screws are manufactured from Titanium conforming to ASTM F136 which is equivalent to the primary predicate Arthrex Distal Radius Plate System, K131474. The Arthrex Low Profile Screws are 2.4 mm in diameter which is equivalent to the primary predicate Arthrex Distal Radius Plate System, K131474. The Arthrex 2.4 mm Volar Distal Radius Plates are provided non-sterile which is equivalent to the primary predicate Arthrex Distal Radius Plate System, K131474. The Arthrex 2.4 mm Volar Distal Radius Plates are also provided sterile (Gamma). The Arthrex Low Profile Screws are provided sterile (Gamma). The non-sterile Arthrex 2.4 mm Volar Distal Radius Plates have an

	unlimited shelf-life which is equivalent to the primary predicate Arthrex Distal Radius Plate System, K131474. The sterile Arthrex 2.4 mm Volar Distal Radius Plates and Arthrex Low Profile Screws are labeled with a 5-year shelf-life. The Arthrex 2.4 mm Volar Distal Radius Plate System was evaluated for MR Conditional labeling. The primary predicate Arthrex Distal Radius Plate System, K131474 was not evaluated for MR Safety. The Arthrex 2.4 mm Volar Distal Radius Plate System is substantially equivalent to the predicate devices cleared under K131474, with minor modifications with no change to intended use or function. Any differences between the Arthrex 2.4 mm Volar Distal Radius Plate System and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex 2.4 mm Volar Distal Radius Plate System is substantially equivalent to the predicate devices cleared under K131474 in which the basic design features and intended use are the same. Any differences between the Arthrex 2.4 mm Volar Distal Radius Plate 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 4-Point Bend strength of the Arthrex 2.4 mm Volar Distal Radius Plates are 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.