February 3, 2021

Arthrex Inc.
Samantha Passman
Regulatory Affairs Associate Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K203294
Trade/Device Name: Arthrex Pilon Fusion 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: November 2, 2020
Received: November 9, 2020

Dear Samantha Passman:

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, MPH
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

List of Cleared Devices in K203294

List of Cleared Devices in K203294

1. Arthrex Pilon Fusion Plates
2. Arthrex Low Profile

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)*

K203294

Device Name

Arthrex Pilon Fusion Plates

Indications for Use *(Describe)*

The Arthrex Pilon Fusion Plates are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, tibia, and calcaneous.

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
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)*

K203294

Device Name
Arthrex Low Profile Screws

Indications for Use *(Describe)*

The Arthrex Low Profile Screws (3.5mm 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.

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	January 8, 2021
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Samantha Passman Regulatory Affairs Associate Specialist 1-239-643-5553, ext. 71595 Samantha.passman@arthrex.com
Name of Device	Arthrex Pilon Fusion System
Common Name	Plate, Fixation, Bone (Primary) Screw, Fixation, Bone
Product Code	HRS (Primary), HWC
Classification Name	21 CFR § 888.3030 (Primary): Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3040: Smooth or threaded metallic bone fixation fastener; Class II
Regulatory Class	II
Predicate Device	K151732: Arthrex Fracture Plates (Primary Predicate) K141735: Arthrex Ankle Fusion Plating System (Additional Predicate)
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Pilon Fusion Plate System and additional longer length Arthrex Low Profile Screws. This submission is also intended to document the modifications made to the previously cleared 3.5 mm Arthrex Low Profile Screws cleared under K103705, K111253, K123241, K131474, K143614, and K150456.
Device Description	The Arthrex Pilon Fusion Plate System are a family of contoured plates and screws. The Arthrex Pilon Fusion Plates are manufactured from Titanium conforming to ASTM F136 and are available in a variety of configurations. The Arthrex Pilon Fusion Plates are intended to be used with solid locking and non-locking Low Profile Screws. The proposed plates are sold sterile or non-sterile and single use. The proposed Arthrex Low Profile Screws are offered in a 3.5mm diameter, length range of 85 to 120 mm, in a solid and fully threaded design. The screws are manufactured from Titanium conforming to ASTM F136 and are sold sterile or non-sterile and single-use.
Indications for Use	The Arthrex Pilon Fusion Plates are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, tibia, and calcaneous. The Arthrex Low Profile Screws (3.5mm 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.
Performance Data	Insertion torque and failure torque, per ASTM F543, was conducted to demonstrate that the proposed screws perform statistically equivalent to the predicate. In-vitro testing (4-point bend) per ASTM F382 Annex A1 & A2 was

	performed on the proposed plates to demonstrate that the performance of the proposed plates is substantially equivalent to that of the predicate devices. Pull-out testing and insertion torque/failure torque testing was conducted on the previously cleared 3.5 mm Arthrex Low Profile Screws to demonstrate that the design modifications do not affect the safety or performance. MR compatibility testing was also conducted per ASTM F2052-15 (displacement force), ASTM F2213-17 (torque), ASTM F2119-13 (image artifact), and ASTM F2182-11a (RF Heating).
Conclusion	The Arthrex Pilon Fusion System is substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the proposed devices and the predicate devices are considered minor and do not raise different questions concerning safety or effectiveness. The submitted data for the proposed Arthrex Pilon Fusion System demonstrates that the bending strength and the torque of the proposed devices 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 devices are substantially equivalent to the currently marketed predicate device.