



October 16, 2019

Arthrex, Inc.
Rebecca R. Homan
Senior Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K190953

Trade/Device Name: Arthrex Minimally Invasive Ankle Fusion Plate
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: April 5, 2019
Received: April 11, 2019

Dear Rebecca R. 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,

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

Indications for Use

510(k) Number (if known)

K190953

Device Name

Arthrex Minimally Invasive Ankle Fusion Plate

Indications for Use (Describe)

The Arthrex Minimally Invasive Ankle Fusion Plate is intended to be used for fixation of bone fractures and fusions in the foot and ankle. The Arthrex Minimally Invasive Ankle Fusion Plate is to be used with the Arthrex Low Profile Screws.

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	October 15, 2019
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Caroline Bloemker Senior Regulatory Affairs Associate 1-239-643-5553, ext. 71639 caroline.bloemker@arthrex.com
Name of Device	Arthrex Minimally Invasive Ankle Fusion Plate
Common Name	Plate, Fixation, Bone
Product Code	HRS, HWC
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliance and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	K141735: Arthrex Ankle Fusion Plating System K040907: Arthrex Small Fragment Plates and Screws (Reference) K150456: Arthrex Plates, Screws, and Staples (Reference)
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Minimally Invasive Ankle Fusion Plate.
Device Description	The Arthrex Minimally Invasive Ankle Fusion Plate is a Titanium bone fixation device intended to be permanently implanted. The implant is contoured with a tapered proximal end and contoured bend on the distal end. The implant has a 3-hole design and is 1.74 inches in length. The implant is single-use and may be available in sterile and non-sterile versions.
Indications for Use	The Arthrex Minimally Invasive Ankle Fusion Plate is intended to be used for fixation of bone fractures and fusions in the foot and ankle. The Arthrex Minimally Invasive Ankle Fusion Plate is to be used with the Arthrex Low Profile Screws.
Performance Data	Static and fatigue bending strength testing was conducted in accordance with ASTM F382-17 to demonstrate that the Arthrex Minimally Invasive Ankle Fusion Plate performed statistically equivalent to the predicate device cleared under K141735 Arthrex Ankle Fusion Plating System on August 15, 2014. MRI force, torque, and image artifact testing were conducted in accordance with FDA guidance <i>Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment</i> . Bacterial Endotoxins Test (BET) was performed on the Arthrex Minimally Invasive Ankle Fusion Plate utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820. The testing conducted demonstrates that the Arthrex Minimally Invasive Ankle Fusion Plate meets pyrogen limit specifications.
Conclusion	The Arthrex Minimally Invasive Ankle Fusion Plate 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 of safety or effectiveness.

Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the Arthrex Minimally Invasive Ankle Fusion Plate is substantially equivalent to the currently marketed predicate device.