July 6, 2020

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

Re: K201235
Trade/Device Name: Arthrex MaxForce MTP Compression Plates and Screws
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: May 4, 2020
Received: May 7, 2020

Dear Rebecca 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,

For

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

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)*
K201235

Device Name
Arthrex MaxForce MTP Compression Plates and Screws

Indications for Use *(Describe)*
The Arthrex MaxForce MTP Compression Plates are intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the Forefoot.

The Arthrex Low Profile Screws (2.0-3.0mm 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 screws may be used with the Arthrex Low Profile Plates, Small Fragment Plates and MaxForce MTP Compression Plates.

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 Plates, Small Fragment Plates, Humeral Fracture Plates, Osteotomy Plates, and MaxForce MTP Compression 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	July 6, 2020
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Rebecca R. Homan Regulatory Affairs Specialist 1-239-643-5553, ext. 73429 rebecca.homan@arthrex.com
Name of Device	Arthrex MaxForce MTP Compression Plates and Screws
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 Classification); 21 CFR 888.3040: Smooth or Threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Devices	K130510: Arthrex Compression Plates (Primary Predicate) K111253: Arthrex Distal Extremity Plate System K103705: Arthrex Low Profile Screws
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex MaxForce MTP Compression Plates and Screws.
Device Description	The Arthrex MaxForce MTP Compression Plates and Screws consists of a series of plates and screws of varying lengths and diameters. The plates are contoured to fit the various aspects of the metatarsals including Petite, Standard, Long, X-Long and Revision with 0° and 5° Valgus and Dorsiflex in left and right configurations. The plates are manufactured from titanium alloy conforming to ASTM F136. The plates are attached to bone with 3.0 mm cortical, 3.0 mm cortical, hybrid and 3.0 mm variable locking screws. The screws range from 3.0 mm to 3.5 mm in diameter and from 10 mm to 26 mm in length. The screws are manufactured from titanium alloy conforming to ASTM F136. The plates and screws are sold non-sterile and single-use.
Indications for Use	The Arthrex MaxForce MTP Compression Plates are intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the Forefoot. The Arthrex Low Profile Screws (2.0-3.0mm 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 screws may be used with the Arthrex Low Profile Plates, Small Fragment Plates and MaxForce MTP Compression Plates. 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 Plates, Small Fragment Plates, Humeral Fracture Plates, Osteotomy Plates, and MaxForce MTP Compression Plates.

Performance Data	Engineering analysis, Static Four-Point Bend (ASTM F382), Four-Point Bend Fatigue (ASTM F382), and plate/instrument compression testing were conducted on the subject plates. Pull-out strength testing (ASTM F543), torsional strength testing (ASTM F543) and Insertion Torque testing were conducted on the subject screws. The testing demonstrates that the Arthrex MaxForce MTP Compression Plates and Screws performs statistically equivalent to the predicate devices cleared under K130510, K111253 and K103705. 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.
Technological Comparison	The Arthrex MaxForce MTP Compression Plates and Screws are substantially equivalent to the predicate devices in which the basic design features, intended use, fundamental scientific technology, indications for use, sterility, packaging, and shelf-life are identical. The Arthrex MaxForce MTP Compression Plates are contoured to fit the various aspects of the metatarsals including Petite, Standard, Long, X-Long and Revision with 0° and 5° Valgus and Dorsiflex in left and right configurations. The predicate Arthrex Compression Plates cleared under K130510 are contoured to fit the various aspects of the foot, ankle, hand and wrist including Square, Linear, T- configurations. The predicate Arthrex Contoured Plates cleared under K111253 are contoured to fit the metatarsals including Petite, Standard, and Long in left and right configurations. The Arthrex MaxForce MTP Compression Plates and Screws are manufactured from titanium; whereas the predicate Arthrex Compression Plates cleared under K130510 are manufactured from stainless steel. However, the titanium alloy used to manufacture the Arthrex MaxForce MTP Compression Plates and Screws is identical is identical to the titanium alloy cleared for the Arthrex Contoured Plates cleared under K111253. The Arthrex MaxForce MTP Compression Plates and Screws were evaluated for MR Conditional labeling; whereas the predicate devices were not evaluated for MR Conditional labeling.
Conclusion	The Arthrex MaxForce MTP Compression Plates and Screws are 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 Arthrex MaxForce MTP Compression Plates and Screws MR compatibility testing supports the devices MR Conditional labeling. There is no increased risk from this difference in technology. The submitted mechanical testing data demonstrates that the Static Four-Point Bend, Four-Point Bend Fatigue, Compression Force, Compression Distance, Pull-out and Torque strength of the Arthrex MaxForce MTP Compression Plates and Screws 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 devices are substantially equivalent to the currently marketed predicate devices.