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

October 3, 2019

Re: K191344
Trade/Device Name: Arthrex Mini Comprehensive Fixation System - 2.0mm & 2.4mm Module
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: August 29, 2019
Received: August 30, 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,

For, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191344

Device Name
Arthrex Mini Comprehensive Fixation System – 2.0mm & 2.4mm Module

Indications for Use *(Describe)*
The Arthrex Mini Comprehensive Fixation System Plates (2.0-2.4 mm) are intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone. Examples include, but are not limited to, the hand, wrist, foot, and ankle. The Arthrex Mini Comprehensive Fixation System Plates are to be used with the Arthrex Mini Comprehensive Fixation System Screws (2.0-2.4 mm solid).

The Arthrex Mini Comprehensive Fixation System Screws (2.0-2.4 mm solid) are intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone. Examples include, but are not limited to, the hand, wrist, foot, and ankle. The Arthrex Mini Comprehensive Fixation System Screws are to be used with the Arthrex Mini Comprehensive Fixation System Plates (2.0-2.4 mm).

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 or 510(k) Statement

Date Prepared	August 29, 2019
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Rebecca R. Homan Senior Regulatory Affairs Associate 1-239-643-5553, ext. 73429 rebecca.homan@arthrex.com
Name of Device	Arthrex Mini Comprehensive Fixation System – 2.0mm & 2.4mm Module
Common Name	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Product Code	HRS; HWC
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	K063049: Synthes (USA) Modular Mini Fragment LCP System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Mini Comprehensive Fixation System – 2.0mm & 2.4mm Module.
Device Description	The Arthrex Mini Comprehensive Fixation System – 2.0mm & 2.4mm Module consists of a series of plates and screws of varying lengths and thickness. The plates are contoured to fit the various aspects of the hand, wrist, foot and ankle including Straight, T-, Y-, V-, Cage, Triangular and Bridge. The plates are attached to bone with 2.0 mm and 2.4 mm cortical and variable locking screws. The screws range from 2.0 mm to 2.4 mm in diameter and from 6 mm to 40 mm in length. The plates and screws are manufactured from titanium. The plates and screws are sold non-sterile and single-use.
Indications for Use	The Arthrex Mini Comprehensive Fixation System Plates (2.0-2.4 mm) are intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone. Examples include, but are not limited to, the hand, wrist, foot, and ankle. The Arthrex Mini Comprehensive Fixation System Plates are to be used with the Arthrex Mini Comprehensive Fixation System Screws (2.0-2.4 mm solid). The Arthrex Mini Comprehensive Fixation System Screws (2.0-2.4 mm solid) are intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone. Examples include, but are not limited to, the hand, wrist, foot, and ankle. The Arthrex Mini Comprehensive Fixation System Screws are to be used with the Arthrex Mini Comprehensive Fixation System Plates (2.0-2.4 mm).
Performance Data	Pull-out (ASTM F543), insertion torque/failure torque, static four-point bend (ASTM F382) and four-point bend fatigue testing (ASTM F382) was conducted to demonstrate that the proposed Arthrex Mini Comprehensive Fixation System – 2.0mm & 2.4mm Module performs statistically equivalent to the predicate.
Conclusion	The Arthrex Mini Comprehensive Fixation System – 2.0mm & 2.4mm Module 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 concerning safety or effectiveness. The submitted mechanical testing data demonstrates that the pull-out, torque, bending strength and the fatigue strength of the proposed devices are substantially equivalent to that of the predicate device 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 device.