June 29, 2022

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

Re: K220937
Trade/Device Name: Arthrex Mini Fragment 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: March 18, 2022
Received: March 31, 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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220937

Device Name

Arthrex Mini Fragment System

Indications for Use *(Describe)*

The Arthrex Mini Fragment System is indicated for fracture fixation, reconstruction, replantation, stabilization, reduction, fusions, osteotomies, mal-unions, and non-unions of small bones and small bone fragments including normal and osteopenic bones in adult and adolescent (12 - 21 year) patients. The system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

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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K220937
510(k) Summary

Date Prepared	June 28, 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 Mini Fragment System
Common Name	Plate, fixation, bone
Product Code	HRS (Primary), 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 fastener
Regulatory Class	II
Primary Predicate Device	K191412: VariAx 2 Mini Fragment System
Additional Predicate Device	K191344: Arthrex Mini Comprehensive Fixation System – 2.0 & 2.4 Module K140814: Smith & Nephew EVOS Mini-Fragment Plating System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Mini Fragment System.
Device Description	The proposed Arthrex Mini Fragment System consists of a series of plates and screws of varying lengths and thicknesses. Each plate provides locking screw fixation. The proposed screws are a family of locking and non-locking screws. The proposed plates and screws are manufactured from Titanium Alloy. The proposed plates and screws are sold non-sterile and single-use.
Indications for Use	The Arthrex Mini Fragment System is indicated for fracture fixation, reconstruction, replantation, stabilization, reduction, fusions, osteotomies, mal-unions, and non-unions of small bones and small bone fragments including normal and osteopenic bones in adult and adolescent (12-21 years) patients. The system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.
Performance Data	Arthrex conducted Static 4-Point Bend (ASTM F382-17), 4-Point Fatigue Bend (ASTM F382-17), Pull-out (ASTM F543-17), Failure Torque, Insertion Torque (ASTM F543-17) and testing to demonstrate that the Arthrex Mini Fragment System performs statistically equivalent to the predicate Stryker VariAx 2 Mini Fragment System, K191412. 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 Mini Fragment System is substantially equivalent to the predicate devices cleared under K191412 in which the basic design features, intended use, fundamental scientific technology, shelf-life, and sterility are identical. The Arthrex Mini Fragment System is manufactured from Titanium Alloy conforming to ASTM F136 (for Plates) and ASTM F136/F1472 (for Screws). The primary predicate plates and screws cleared under the Stryker VariAx 2 Mini Fragment System, K191412 are manufactured from titanium alloy and unalloyed titanium (standards unknown). The proposed Arthrex Mini Fragment System plates are offered in lengths ranging from 35.2 – 141.1 mm . The primary predicate plates cleared under the Stryker VariAx 2 Mini Fragment System, K191412 are offered in lengths ranging from 22 – 176 mm. The proposed Arthrex Mini Fragment System screws are offered in diameters of 2.0 mm, 2.4mm, and 2.7 mm. The primary predicate screws cleared under the Stryker VariAx 2 Mini Fragment System, K191412 are offered in diameters of 2.0 mm, 2.4 mm, and 2.7 mm. The Arthrex Mini Fragment System was evaluated for MR Conditional labeling as were the predicate device cleared under K191412. The Arthrex Mini Fragment is substantially equivalent to the predicate devices cleared under K191412, with minor modifications with no change to intended use or function. Any differences between the Arthrex Mini Fragment System and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex Mini Fragment System is substantially equivalent to the predicate devices cleared under K191412 in which the basic design features and intended use are the same. Any differences between the Arthrex Mini Fragment 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 Static 4-Point Bend Strength, 4-Point Bend strength, Pull-Out and Failure Torque/Insertion Torque of the Arthrex Mini Fragment System is 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 devices.