February 10, 2020

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

Re: K193156
Trade/Device Name: Arthrex Mini Comprehensive Fixation System - 1.0mm Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 11, 2019
Received: November 14, 2019

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,

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)*
K193156

Device Name
Arthrex Mini Comprehensive Fixation System - 1.0 mm Screws

Indications for Use *(Describe)*
The Arthrex Mini Comprehensive Fixation System Screws (1.0 mm solid) are intended for use in selective trauma, reconstructive procedures, and general surgery of the hand and wrist.

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	February 7, 2020
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 – 1.0mm Screws
Common Name	Screw, fixation, bone
Product Code	HWC
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	K030310: Synthes Stainless Steel Modular Hand System
Reference Devices	K191326: Arthrex Mini Comprehensive Fixation System – 1.4mm & 1.6mm Module K191344: Arthrex Mini Comprehensive Fixation System – 2.0mm & 2.4mm Module K050607: Synthes 1.0mm Ti. Cortex, Self-drilling Screws (hand & Neuro)
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Mini Comprehensive Fixation System – 1.0mm Screws.
Device Description	The Arthrex Mini Comprehensive Fixation System – 1.0mm Screws are manufactured from titanium. The screws are headed and self-tapping. The screws are available as fully threaded, solid screws. The screws are 1.0mm in diameter and from 6 mm to 14 mm in length (in 1 mm increments). The screws are sold non-sterile and single-use.
Indications for Use	The Arthrex Mini Comprehensive Fixation System Screws (1.0mm solid) are intended for use in selective trauma, reconstructive procedures, and general surgery of the hand and wrist.
Performance Data	Pull-out and torque testing was conducted in accordance with ASTM F543 to demonstrate that the proposed Arthrex Mini Comprehensive Fixation System – 1.0mm Screws perform statistically equivalent to the predicate device, K030310. Arthrex performed an engineering analysis to conclude that the Insertion Torque/Failure Torque values of the Arthrex Mini Comprehensive Fixation System – 1.0mm Screws were acceptable. 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 Comprehensive Fixation System – 1.0mm Screws are substantially equivalent to the predicate devices in which the basic design features, fundamental scientific technology, intended use, indications for use, sterility, packaging, and shelf-life are identical.

	The Arthrex Mini Comprehensive Fixation System – 1.0mm Screws are manufactured from titanium; whereas the predicate device, K030310 is manufactured from stainless steel. However, the titanium alloy used to manufacture the Arthrex Mini Comprehensive Fixation System – 1.0mm Screws is identical is identical to the titanium alloy cleared in K191326 and K191344. The Arthrex Mini Comprehensive Fixation System – 1.0mm Screws were evaluated for MR Conditional labeling; whereas the predicate device was not evaluated for MR Conditional labeling.
Conclusion	The Arthrex Mini Comprehensive Fixation System – 1.0mm 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 device and the predicate device are considered minor and do not raise different questions concerning safety or effectiveness. The Arthrex Mini Comprehensive Fixation System – 1.0mm 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 pull-out and torque 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.