September 19, 2022

Arthrex Inc.
Rebecca Homan
Team Lead, Regulatory Affairs-Product Development
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K220839
Trade/Device Name: Arthrex Compression FT Pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 2, 2022
Received: March 23, 2022

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,

Jesse Muir -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220839

Device Name
Arthrex Compression FT Pins

Indications for Use *(Describe)*

The Arthrex Compression FT pins (1.9 mm) are intended for small bone fracture and osteotomy fixation in the hand, wrist, foot, ankle and knee.

The Arthrex Compression FT pins (2.4 mm) are intended for fixation of small bone fragments, such as apical fragments, osteochondral fragments and cancellous fragments. Specific applications include the following:

- Osteochondral fragments
- Apical fragments (radial head, patellar rim, navicular, metacarpal/metatarsal)
- Cancellous fragments
- Carpal, metacarpal, and small hand bone
- Tarsal and metatarsals
- Phalanges
- Intra-articular fractures
- Ankle
- Proximal and distal humerus
- Proximal and distal radius
- Proximal and distal ulna
- Osteochondral fixation and fractures
- Osteochondritis Dissecans
- Fixation of fractures and osteotomies about the knee
- Oblique fractures of the fibula
- Reconstructive surgeries of the foot
- Malleolar fixation

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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K220839

510(k) Summary

Date Prepared	September 16, 2022
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Rebecca R. Homan Team Lead, Regulatory Affairs – Product Development 1-239-643-5553, ext. 73429 rebecca.homan@arthrex.com
Name of Device	Arthrex Compression FT Pins
Common Name	Screw, fixation, bone
Product Code	HWC
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fastener
Regulatory Class	II
Primary Predicate Device	K132217: Arthrex Compression FT Screws
Additional Predicate Devices	K182361: Arthrex Compression FT Screws
Reference Devices	K201132: Arthrex Compression Screws K210994: Arthrex Beveled FT Screws
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Compression FT Pins.
Device Description	The Arthrex Compression FT Pins are a family of solid, fully threaded, self-tapping, tapering head with and without a snap-off function designed to provide fixation of fractures, osteotomies and arthrodesis. The pins are offered in two diameters: 1.9 mm and 2.4 mm, and range in lengths from 10 mm to 50 mm. The pins are manufactured from Titanium Alloy, conforming to ASTM F136. The pins are sold sterile and non-sterile and are single use.
Indications for Use	The Arthrex Compression FT Pins (1.9 mm) are intended for small bone fracture and osteotomy fixation in the hand, wrist, foot, ankle and knee. The Arthrex Compression FT Pins (2.4 mm) are intended for fixation of small bone fragments, such as apical fragments, osteochondral fragments and cancellous fragments. Specific applications include the following: • Osteochondral fragments (talar vault, femoral condyle) • Apical fragments (radial head, patellar rim, navicular, metacarpal/metatarsal) • Cancellous fragments (talus) • Carpal, metacarpal, and small hand bone • Tarsal and metatarsals • Phalanges • Intra-articular fractures • Ankle • Proximal and distal humerus • Proximal and distal radius • Proximal and distal ulna • Osteocondral fixation and fractures • Osteochondritis Dissecans • Fixation of fractures and osteotomies about the knee • Oblique fractures of the fibula

	• Reconstructive surgeries of the foot • Malleolar fixation
Performance Data	Arthrex conducted Axial Pull-out (ASTM F543-17), Compression, Failure Torque/ Insertion Torque (ASTM F543-17), Snapping and Shear testing to demonstrate that the 2.4 mm Arthrex Compression FT Pins perform statistically equivalent to the primary predicate devices cleared under K132217 and additional predicate devices cleared under K182361. Arthrex performed engineering analyses to conclude that the Failure Torque and Insertions Torque values of the Arthrex Compression FT Pins were acceptable. Arthrex used the Safety and Performance Based Pathway to support substantial equivalence of the Axial Pull-out of the 1.9 mm Arthrex Compression FT Pins. 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*. Bacterial Endotoxins Test (BET) was performed on the Arthrex Compression FT Pins utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2019, USP <161>, USP <85>, EP 2.6.14. The testing conducted demonstrates that the sterile devices within the Arthrex Compression FT Pins meet pyrogen limit specifications. Cytotoxicity, Sensitization, Irritation, Genotoxicity, Systemic Toxicity, Subchronic/Subacute Toxicity, Implantation and Material Characterization testing was conducted on the devices within the Arthrex Compression FT Pins in accordance with ISO 10993-1:2018. Assessment of physical product attributes including product, design, size, and materials has determined that the Arthrex Compression FT Pins do not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	The Arthrex Compression FT Pins are substantially equivalent to the primary predicate devices cleared under K132217; additional predicate devices cleared under K182361; and reference devices cleared under K201132 and K210994 in which the basic design features, intended use, fundamental scientific technology, materials, sterility, packaging and shelf-life are identical. The Arthrex Compression FT Pins are a family of solid, fully threaded, self-tapping, tapering head with a snap-off design. The pins are offered in two diameters: 1.9 mm and 2.4 mm, and range in lengths from 10 mm to 50 mm. The pins are manufactured from Titanium Alloy. The pins are sold sterile and non-sterile and are single use.

	The primary predicate device Arthrex Compression FT Screws cleared under K132217 are fully threaded, cannulated screws with self-tapping, tapering head. The screws were cleared in diameters ranging from 2.5 mm to 4.0 mm and lengths ranging from 8 mm to 50 mm. The screws are manufactured from Titanium Alloy. The screws are sold non-sterile and are single use. The additional predicate device Arthrex Compression FT Screws cleared under K182361 are fully threaded, cannulated screws with self-tapping, tapering head. The screws were cleared in diameters ranging from 2.5 mm to 4.0 mm and lengths ranging from 32 mm to 60 mm. The screws are manufactured from Titanium Alloy. The screws are sold non-sterile and are single use. The reference device Arthrex Compression Screws cleared under K201132 are fully threaded, cannulated screws with self-tapping, tapering head. The screws were cleared in diameters ranging from 2.4 mm to 4.5 mm and lengths ranging from 10 mm to 80 mm. The screws are manufactured from Titanium Alloy and Stainless Steel. The screws are sold sterile and non-sterile and are single use. The Arthrex Compression FT Pins are sold sterile and non-sterile as were the reference devices cleared under K201132 and K210994. The Arthrex Compression FT Pins were evaluated for MR Conditional labeling as were the reference devices cleared under K201132 and K210994. The Arthrex Compression FT Pins are substantially equivalent to the primary predicate devices cleared under K132217; additional predicate devices cleared under K182361; and reference devices cleared under K201132 and K210994, with minor dimensional modifications with no change to intended use or function. Any differences between the Arthrex Compression FT Pins and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex Compression FT Pins are substantially equivalent to the primary predicate devices cleared under K132217; additional predicate devices cleared under K182361; and reference devices cleared under K201132 and K210994; in which the basic design features and intended use are the same. Any differences between the Arthrex Compression FT Pins 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 Axial Pull-out, Compression, Shear and Torsion strength of the Arthrex Compression FT Pins System 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 device is substantially equivalent to the currently marketed predicate devices.