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

December 18, 2018

Re: K182361
Trade/Device Name: Arthrex Compression FT 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 16, 2018
Received: November 19, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Digitally signed by Jesse Muir -S
Date: 2018.12.18 14:46:11 -05'00'

For
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

US 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)*

K182361

Device Name

Arthrex Compression FT Screws

Indications for Use *(Describe)*

The Arthrex Compression FT Screws 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

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	December 17, 2018
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Rebecca R. Homan Regulatory Affairs Associate 1-239-643-5553, ext. 73429 rebecca.homan@arthrex.com
Name of Device	Arthrex Compression FT 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	K132217: Arthrex Compression FT Screws K141735: Arthrex Ankle Fusion Plating System
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for a line extension to the Arthrex Compression Screws family cleared under K132217.
Device Description	The Arthrex Compression FT Screws are a family of titanium, cannulated, compression screws that are offered in a diameter range of 2.5 to 4.0mm, length range of 32 to 60mm, in a fully threaded design.
Indications for Use	The Arthrex Compression FT Screws 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 bones • 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
Technical Comparison	The Arthrex Compression FT Screws are substantially equivalent to the predicate devices in which the basic design features, intended use, indications for use, material, biocompatibility, method of sterilization, packaging, and shelf-life are the same. The Arthrex Compression FT Screws are a line extension to the predicate devices, which include minor dimensional modifications with no change in intended use or function. Any differences between the Arthrex Compression FT Screws and

	the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Performance Data	Push-out, torque and compression testing were conducted to demonstrate that the proposed longer Arthrex Compression FT Screws perform statistically equivalent to the predicate.
Conclusion	The longer Arthrex Compression FT Screws are 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 of safety or effectiveness. Based on the indications for use, technological characteristics, and data submitted, Arthrex Inc. has demonstrated that the proposed device is substantially equivalent to the currently marketed predicate device.