June 1, 2021

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

Re: K210994
Trade/Device Name: Arthrex Beveled 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: April 1, 2021
Received: April 2, 2021

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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210994

Device Name
Arthrex Beveled FT Screws

Indications for Use *(Describe)*

The Arthrex Beveled FT Screws are indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Mono or Bi-Cortical osteotomies in the foot or hand
- Distal or Proximal metatarsal or metacarpal osteotomies
- Weil osteotomy
- Fusion of the first metatarsophalangeal joint and interphalangeal joint
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)
- Akin type osteotomy
- Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
- Calcaneus/cuboid arthrodesis
- Talar/navicular arthrodesis

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	April 1, 2021
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Rebecca R. Homan Senior Regulatory Affairs Specialist 1-239-643-5553, ext. 73429 rebecca.homan@arthrex.com
Name of Device	Arthrex Beveled FT Screws
Common Name	Screw, fixation, bone
Product Code	HWC
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fastener
Regulatory Class	II
Predicate Device	K162353: Wright Medical MICA Screw System
Reference Device	K201132: Arthrex Compression Screws
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Beveled FT Screws.
Device Description	The Arthrex Beveled FT Screws are fully threaded, cannulated screws with self-tapping, tapering head. The screws will be offered in three diameters: 3.5 mm, 4.0 mm and 4.5 mm, and will range in lengths from 12 mm to 60 mm. The screws are manufactured from Titanium Alloy, conforming to ASTM Standards F1472. The screws are sold sterile and non-sterile and are single use.
Indications for Use	The proposed Arthrex Beveled FT Screws are indicated for fixation of bone fractures or for bone reconstruction. Examples include: • Mono or Bi-Cortical osteotomies in the foot or hand • Distal or Proximal metatarsal or metacarpal osteotomies • Weil osteotomy • Fusion of the first metatarsophalangeal joint and interphalangeal joint • Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.) • Akin type osteotomy • Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus • Calcaneus/cuboid arthrodesis • Talar/navicular arthrodesis
Performance Data	Arthrex conducted Pull-out, Push-out, Failure Torque, Insertion Torque (ASTM F543-17) and 3-Point Bend (ASTM F382-17) testing to demonstrate that the Arthrex Beveled FT Screws perform statistically equivalent to the predicate devices cleared under K162353 and K201132. Arthrex performed engineering analyses to conclude that the Failure Torque and Insertions Torque values of the Arthrex Beveled FT 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*. Bacterial Endotoxins Test (BET) was performed on the Arthrex Beveled FT Screws utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14. The testing conducted demonstrates that the sterile devices within the Arthrex Beveled FT Screws 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 Beveled FT Screws in accordance with ISO 10993-1:2018. Assessment of physical product attributes including product, design, size, and materials has determined that the Arthrex Beveled FT Screws do not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	The Arthrex Beveled FT Screws are substantially equivalent to the predicate devices cleared under K162353 and K201132 in which the basic design features, intended use, fundamental scientific technology, materials, sterility, packaging and shelf-life are identical. The Arthrex Beveled FT Screws are fully threaded, cannulated screws with self-tapping, tapering head. The screws will be offered in three diameters: 3.5 mm, 4.0 mm and 4.5 mm, and will range in lengths from 12 mm to 60 mm. The predicate Wright Medical MICA Screws cleared under K162353 are fully threaded, cannulated screws with self-tapping, tapering head. The screws were cleared in diameters ranging from 3.0 mm to 4.0 mm and lengths ranging from 32 mm to 48 mm. The predicate 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 Arthrex Beveled FT Screws were evaluated for MR Conditional labeling as were the predicate devices cleared under K201132. The Arthrex Beveled FT Screws are substantially equivalent to the predicate devices cleared under K162353 and K201132, with minor dimensional modifications with no change to intended use or function. Any differences between the Arthrex Beveled FT Screws and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex Beveled FT Screws are substantially equivalent to the predicate devices cleared under K162353 and 201132; in which the basic design features and intended use are the same. Any differences between the Arthrex Beveled FT Screws 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 Pull-out, Push-out, and 3-Point Bend strength of the Arthrex Beveled FT Screws 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.