November 18, 2020

Arthrex Inc.
Jessica L. Singelais
Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108

Re: K202535
Trade/Device Name: Arthrex FastThread Interference Screw
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, HWC
Dated: October 22, 2020
Received: October 26, 2020

Dear Ms. Singelais:

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,

Laura C. Rose, Ph.D.
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)*
K202535

Device Name
Arthrex FastThread Interference Screw

Indications for Use *(Describe)*
The Arthrex FastThread Interference Screws are intended to be used for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone. Interference fixation is appropriate for surgeries of the knee, shoulder, elbow, ankle, foot, and hand/wrist where the sizes offered are patient appropriate; specifically,

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis, Posterior Cruciate Ligament Repair, MPFL Repair/Reconstruction

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/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	October 22, 2020
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Jessica L. Singelais Regulatory Affairs Specialist 1-239-598-4302, ext. 73091 Jessica.singelais@arthrex.com
Name of Device	Arthrex FastThread Interference Screw
Common Name	Fastener, Fixation, Biodegradable, Soft Tissue Screw, fixation, bone
Product Code	MAI, HWC
Classification Name	888.3030 Single/multiple component metallic bone fixation appliances and accessories 888.3040 Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	K180662: Arthrex FastThread Interference Screw
Reference Device	K201749: Arthrex SwiveLock Suture Anchor K173240: Arthrex PushLock
Purpose of Submission	This Special 510(k) premarket notification is submitted to expand indications for the Arthrex FastThread Interference Screw cleared under K180662 to include MPFL Repair/Reconstruction.
Device Description	The Arthrex FastThread Interference Screw is a cannulated, fully threaded, bioabsorbable interference screw, manufactured from PLDLA, Biphasic Calcium Phosphate and hydroxyapatite (HA). The screws measure 6-12 mm in diameter and 20-30 mm in length.
Comparison Summary of Technological Characteristics and Modifications Proposed	The proposed and predicate devices (K180662) have the same technological characteristics (device design, sterilization and biocompatibility). Therefore, sterilization and biocompatibility data can be leveraged from the previous clearance. The proposed device modification consists of the addition of the MPFL Repair/Reconstruction indication and an extended shelf life. The shelf-life has been extended using the same methods and protocol reviewed and accepted by FDA in K173240. The Arthrex FastThread Interference Screw is substantially equivalent to the predicate device in which the 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 questions concerning safety or effectiveness.
Indications for Use	The Arthrex FastThread Interference Screws are intended to be used for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone. Interference fixation is appropriate for surgeries of the knee, shoulder, elbow, ankle, foot, and hand/wrist where the sizes offered are patient appropriate; specifically, ***Shoulder:*** Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction ***Foot/Ankle:*** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament

	Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle ***Knee:*** Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis, Posterior Cruciate Ligament Repair, MPFL Repair/Reconstruction ***Elbow:*** Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction ***Hand/Wrist:*** Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/wrist
Performance Data	Mechanical testing demonstrated that the pull-out strength of the proposed Arthrex FastThread Interference Screw met the acceptance criterion established by K201749 for MPFL repair/reconstruction. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Conclusion	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.