Arthrex Inc.
Kristi Frisch
Regulatory Affairs Specialist, Principal
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K231113
Trade/Device Name: Arthrex FiberTak Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 17, 2023
Received: April 19, 2023

Dear Kristi Frisch:

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,

Yu-chieh Chiu -S

Digitally signed by Yu-chieh Chiu -S
Date: 2023.05.17 20:21:18 -04'00'

Yu-Chieh Chiu, Ph.D.
Acting 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)*
K231113

Device Name
Arthrex FiberTak Suture Anchor

Indications for Use *(Describe)*
The Arthrex FiberTak Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures:

- Shoulder: Rotator cuff repair, 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, mid-foot reconstruction, hallux valgus reconstruction, metatarsal ligament repair, and digital tendon transfers
- Knee: Medial collateral ligament repair, lateral collateral ligament repair, patellar tendon, posterior oblique ligament repair, iliotibial band tenodesis, and joint capsule closure, and Medial Patellofemoral Ligament Repair/Reconstruction
- Hand/Wrist: Scapholunate ligament reconstruction, carpal ligament reconstructions, repair/reconstruction of collateral ligaments digital tendon transfers, and carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)
- Elbow: Biceps tendon reattachment, ulnar/radial collateral ligament reconstruction, and lateral epicondylitis repair
- Hip: Gluteal tendon repair

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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.

510(k) Summary

Date Prepared	May 18, 2023
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Kristi Frisch Regulatory Affairs Specialist, Principal Tel 239-598-4302 x73849 Kristi.Frisch@Arthrex.com
Trade Name	Arthrex FiberTak Suture Anchor
Common Name	Suture Anchor
Product Code	MBI
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fastener
Regulatory Class	II
Primary Predicate Device	K203268: Arthrex FiberTak Suture Anchor
Reference Device(s)	K201749: Arthrex SwiveLok Suture Anchor
Purpose of Submission	This Special 510(k) premarket notification is submitted to expand indications of the 2.6 mm FiberTak Suture Anchor to include Medial Patellofemoral Ligament Repair/Reconstruction.
Device Description	The Arthrex FiberTak suture anchor is an 'all-suture' soft-tissue device intended to be used for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip. The anchor is constructed from a hollow braid of polyester with a single loaded suture component composed of UHWMPE or a polyblend of UHMWPE and polyester. The anchor is pre-loaded on a disposable inserter and will be sold sterile for single-use
Indications for Use	The Arthrex FiberTak Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures: • Shoulder: Rotator cuff repair, 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, mid-foot reconstruction, hallux valgus reconstruction, metatarsal ligament repair, and digital tendon transfers • Knee: Medial collateral ligament repair, lateral collateral ligament repair, patellar tendon, posterior oblique ligament repair, iliotibial band tenodesis, joint capsule closure, and Medial Patellofemoral Ligament Repair/Reconstruction • Hand/Wrist: Scapholunate ligament reconstruction, carpal ligament reconstructions, repair/reconstruction of collateral ligaments digital tendon transfers, and carpometacarpal joint arthroplasty (basal thumb joint arthroplasty • Elbow: Biceps tendon reattachment, ulnar/radial collateral ligament reconstruction, and lateral epicondylitis repair • Hip: Gluteal tendon repair

Performance Data	Mechanical testing demonstrated that the pull-out (tensile) strength of the proposed Arthrex FiberTak Suture Anchor met the criteria established by published literature for Medial Patellofemoral Ligament Repair/Reconstruction.
Technological Comparison	The proposed Arthrex Suture Anchor device and predicate device (K203268) have the same technological characteristics (device design, sterilization and biocompatibility). The proposed device modification consists of the addition of the Medial Patellofemoral Ligament Repair/Reconstruction indication. The Arthrex FiberTak Suture Anchor 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.
Conclusion	The Arthrex FiberTak Suture Anchor is substantially equivalent to the predicate devices cleared under K203268 in which the basic design features and intended use are the same. Any differences between the Arthrex FiberTak Suture Anchor 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 Arthrex FiberTak Suture Anchor is substantially equivalent to that of the predicate devices for the desired indication. 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.