November 15, 2023

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

Re: K232973
Trade/Device Name: Arthrex Knee FiberTak® Button 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: September 19, 2023
Received: September 21, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sara S. Thompson -S

For

Jesse Muir, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232973

Device Name
Arthrex Knee FiberTak® Button Suture Anchor

Indications for Use *(Describe)*
The Arthrex Knee FiberTak® Button 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, medial patellofemoral ligament repair/reconstruction, and quadriceps tendon repair
- 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: Acetabular Labral Repair and gluteal tendon repair

.

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	November 14, 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 Knee FiberTak® Button 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	K231330: Arthrex FiberTak® Suture Anchor
Additional Predicate Device	K180768 Arthrex BioComposite SwiveLock®
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to expand indications of the Arthrex Knee FiberTak® Button Suture Anchor to include quadriceps tendon repair.
Device Description	The Arthrex Knee FiberTak® Button 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 Knee FiberTak® Button 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, medial patellofemoral ligament repair/reconstruction, and quadriceps tendon repair • 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: Acetabular Labral Repair and gluteal tendon repair

Performance Data	Ultimate load testing and cyclic displacement was performed on the subject device to demonstrate that the differences do not negatively impact mechanical strength.
Technological Comparison	The proposed Arthrex Knee FiberTak® Button Suture Anchor device and predicate device (K231330) have the same scientific technology, packaging, sterility, shelf-life, and MRI safety labeling. The proposed device modification consists of the addition of the quadriceps tendon repair indication. The additional predicate device Arthrex BioComposite SwiveLock® is comparable in design, intended use and inclusion of the quadriceps tendon repair indication. The Arthrex Knee FiberTak® Button Suture Anchor is substantially equivalent to the predicate device in which the design features and intended uses are identical. 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 Knee FiberTak® Button Suture Anchor is substantially equivalent to the predicate devices cleared under K231330 in which the basic design features and intended use are identical. Any differences between the Arthrex Knee FiberTak ® Button 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 Knee FiberTak® Button 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.