March 20, 2026

Arthrex, Inc.
Ethan Hong
Regulatory Affairs Specialist I
1370 Creekside Blvd.
Naples, Florida 34108

Re: K260561
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: February 19, 2026
Received: February 19, 2026

Dear Ethan Hong:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260561

Please provide the device trade name(s).

Arthrex FiberTak Suture Anchor

Please provide your Indications for Use below.

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

• Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
• Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
• Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, digital tendon transfers, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)
• Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction
• Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Joint Capsule Closure
• Hip: Capsular Repair, Acetabular Labral Repair and Reconstruction, Gluteal Tendon Repair

The 1.8 Knotless FiberTak® Soft Anchor with #2 Suture is also intended to be used for osteochondral fixation and fractures, including surgeries with autograft and allograft tissues, in the Knee and Hip.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Date Prepared	February 17, 2026
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Ethan Hong Title: Regulatory Specialist I Phone: 239-598-4302 ext. 73142 Email: Ethan.Hong@Arthrex.com
Trade Name	Arthrex FiberTak Suture Anchor
Common Name	Suture Anchor
Product Code	MBI
Classification Name	21 CFR 888.3040: Fastener, Fixation, Nondegradable, Soft-Tissue
Regulatory Class	Class II
Primary Predicate Device	K221396: Arthrex FiberTak Suture Anchor
Additional Predicate Devices	K251809: Arthrex FiberTak Suture Anchor K060478: Arthrex Bio-Compression Screw
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the expanded indication of an Arthrex FiberTak Suture Anchor
Device Description	The Arthrex FiberTak Suture Anchors are “all-suture” soft-tissue fixation devices with a push-in design. The anchor (sheath) and connected sutures are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE) and/or Polyester. The subject anchors are impacted into a pilot hole via their inserter. The suture is then manually tensioned to set the anchor by “bulging/bunching” the suture sheath within the pilot hole. The subject devices are provided sterile (Ethylene Oxide), are single-use, and are packaged in a dual-barrier configuration.
Indications for Use	The Arthrex FiberTak Suture Anchor is intended for fixation of suture (soft tissue) to bone in the elbow, shoulder, hand/ wrist, foot/ankle, knee, and hip in the following procedures: Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

	Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, digital tendon transfers, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty) Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Joint Capsule Closure Hip: Capsular Repair, Acetabular Labral Repair and Reconstruction, Gluteal Tendon Repair The 1.8 Knotless FiberTak® Soft Anchor with #2 Suture is also intended to be used for osteochondral fixation and fractures, including surgeries with autograft and allograft tissues, in the Knee and Hip.
Performance Data	Ultimate Load Testing was conducted on the subject device. The test data demonstrates that the subject device performs statistically equivalent to the predicate devices for the intended indications for use.
Technological Comparison	The Arthrex FiberTak Suture Anchor is identical to the primary predicate Arthrex FiberTak Suture Anchor except that it is seeking the additional osteochondral fixation and fractures indication. The subject Arthrex FiberTak Suture Anchor and predicate Arthrex Bio-Compression Screw have similar principle of operations. Any differences between the subject and predicate devices are considered minor and do not raise any new or different questions concerning safety or effectiveness.

Conclusion	The Arthrex FiberTak Suture Anchor is substantially equivalent to the predicate devices. The subject device and primary predicate are of identical designs. Per this 510(k) submission, Arthrex is seeking to add Osteochondral Fixation and Fractures as an additional indication. Any differences between the subject device and the predicate devices are considered minor and do not result in new or different questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex has determined that the subject device is substantially equivalent to the currently marketed predicate devices.