



October 29, 2025

Arthrex, Inc.
Alex Underberg
Regulatory Affairs Specialist, Sr.
1370 Creekside Blvd.
Naples, Florida 34108

Re: K252314

Trade/Device Name: Arthrex SutureTak Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, MAI
Dated: September 29, 2025
Received: September 29, 2025

Dear Alex Underberg:

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.

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

510(k) Number (if known)
K252314

Device Name
Arthrex SutureTak Suture Anchor

Indications for Use (Describe)

The Arthrex BioComposite 2.0 mm SutureTak Suture Anchor is intended for suture (soft tissue) fixation 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, Carpal 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
- 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
- Hip: Acetabular Labral Repair and Reconstruction

The Arthrex PEEK Mini Hip SutureTak is intended to be used for suture (soft tissue) fixation to bone in the hip. Specifically, Acetabular Labral Repair and Reconstruction.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared	07/24/2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Alex Underberg Title: Regulatory Affairs Specialist, Senior Phone: 901-606-4046 Email: Alex.Underberg@Arthrex.com
Trade Name	Arthrex SutureTak Suture Anchor
Common Name	Suture Anchor
Product Code	MBI, MAI
Classification Name	21 CFR 888.3040: Fastener, Fixation, Nondegradable, Soft-Tissue 21 CFR 888.3030: Fastener, Fixation, Biodegradable, Soft-Tissue
Regulatory Class	Class II
Primary Predicate Device	K151092: Arthrex PEEK Mini Hip SutureTak
Additional Predicate Devices	K110660: Arthrex BioComposite 2.0 mm SutureTak K181746: Smith & Nephew Microraptor Knotless Suture Anchor
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the expanded indication of an Arthrex SutureTak Suture Anchors as well as to extend the shelf life of the sterile Arthrex BioComposite 2.0 mm SutureTak from two to four years
Device Description	The fundamental technology of the Arthrex SutureTak Suture Anchor is that the Arthrex SutureTak Suture Anchors are “hard-bodied” fixation devices with anchors manufactured from either BioComposite or PEEK material. The subject anchors are preassembled to suture manufactured from UHMWPE and Polyester. The anchor is first impacted into a pilot hole. Once the anchor is set, the suture is passed around the soft tissue and is fixated via its surgical technique. The devices are provided sterile, are single-use, and are packaged in a dual barrier packaging configuration.
Indications for Use	The Arthrex BioComposite 2.0 mm SutureTak Suture Anchor is intended for suture (soft tissue) fixation to bone in the elbow, shoulder, hand/wrist, foot/ankle, knee, and hip in the following procedures:

	<ul style="list-style-type: none"> • 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, Carpal 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 • 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 • Hip: Acetabular Labral Repair and Reconstruction <p>The Arthrex PEEK Mini Hip SutureTak is intended to be used for suture (soft tissue) fixation to bone in the hip. Specifically, Acetabular Labral Repair and Reconstruction.</p>
<p>Performance Data</p>	<p>Straight Pull testing (method based on ASTM F3690) was conducted on the subject devices to show substantial equivalence for the addition of the proposed indication. The test data demonstrates that the proposed devices perform statistically equivalent to the predicates for the intended indications for use. Insertion and degradation testing were also included per guidance described in FDA guidance document titled “Bone Anchors – Premarket Notification (510(k)) Submissions Guidance for Industry and Food and Drug Administration Staff”. In addition, material stability, packaging, and shelf-life testing were conducted and demonstrate that the proposed device can maintain the proposed shelf-life.</p>
<p>Technological Comparison</p>	<p>The Arthrex PEEK Mini Hip SutureTak and Arthrex BioComposite 2.0 mm SutureTak are identical in design to</p>

	<p>the primary predicate device and predicate SutureTak device. The Arthrex SutureTak Suture Anchors and Smith & Nephew Microraptor Knotless Suture Anchor have similar technologies. Any differences between the subject, primary predicate and additional predicate devices are considered minor and do not raise any new or different questions concerning safety or effectiveness.</p>
<p>Conclusion</p>	<p>The Arthrex SutureTak Suture Anchors are substantially equivalent to the predicate devices. The Arthrex BioComposite 2.0 mm SutureTak is identical to the Arthrex BioComposite 2.0 mm SutureTak with the exception of adding Acetabular Labral Repair and Reconstruction indications and extending its shelf-life. The PEEK Mini Hip SutureTak is identical to the primary predicate with the exception of adding Acetabular Labral Reconstruction indication. The additional predicate device, Smith & Nephew Microraptor Knotless Suture Anchor, has Acetabular Labrum Repair/Reconstruction indications, which is equivalent to the indications Arthrex is seeking. Any differences between the subject, primary predicate and additional 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 devices are substantially equivalent to the currently marketed predicate devices.</p>