July 10, 2025

Arthrex Inc.
Rebecca Homan
Manager, Regulatory Affairs
1370 Creekside Blvd
Naples, Florida 34108

Re: K251145
Trade/Device Name: Arthrex PushLock Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 11, 2025
Received: April 14, 2025

Dear Rebecca Homan:

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, MS
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)*
K251145

Device Name
Arthrex PushLock Suture Anchors

Indications for Use *(Describe)*
The Arthrex PushLock Suture Anchors (2.9 - 4.5 mm) are 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, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, UInar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction, Lateral Epicondylitis repair.

Hip: Capsular repair (2.9 x 15.5 - 24 mm only), acetabular labral repair.

The Arthrex PushLock Suture Anchors (2.5 mm) are intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, and shoulder. Specific indications are listed below:

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

The Arthrex Short Suture Anchors (2.0 - 2.4 mm) are intended to be used for suture (soft tissue) fixation to bone in the hip. Specifically, acetabular labral repair.

The Arthrex Self-Punching PushLock Suture Anchors (3.5 mm) are intended to be used for suture (soft tissue) fixation to bone in the shoulder:

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	04/11/2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Rebecca R. Homan Title: Manager, Regulatory Affairs Phone: 1-239-643-5553, ext. 73429 Email: Rebecca.homan@arthrex.com
Trade Name	Arthrex PushLock Suture Anchors
Common Name	Suture Anchor
Product Code	MBI
Classification Name	21 CFR 888.3040: fastener, fixation, nondegradable, soft tissue
Regulatory Class	II
Primary Predicate Device	K061863: Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family
Additional Predicate Devices	K063479: Arthrex PushLock, K101679 Arthrex PushLock Anchors K151092: Arthrex Short Suture Anchors K221099: Arthrex Self-Punching PushLock Suture Anchors
Reference Devices	K093912: Arthrex Tibial GraftBolt K181513: Arthrex PushLock Tenodesis Anchor
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain FDA clearance for the subject Arthrex PushLock Suture Anchors sterilized using the Arthrex X-ray radiation sterilization process.
Device Description	The Arthrex PushLock Suture Anchor is a two piece “push-in” suture anchor device comprised of a polyetheretherketone (PEEK) anchor body with a polyetheretherketone (PEEK) eyelet pre-loaded on a disposable inserter. The anchors are threaded and range from 2.0 mm to 4.5 mm in diameter and 8.6 mm to approximately 24 mm in length. The device is sold sterile and is single-use. The Arthrex Self-Punching PushLock Suture Anchor is a "push-in" suture anchor comprised of a polyetheretherketone (PEEK) anchor body with a polyetheretherketone (PEEK) eyelet pre-loaded on a disposable inserter. The anchor body is fully threaded and

	barbed. The anchor is 3.5 mm in diameter and 19.8 mm in length. The device is sold sterile and is single-use.
Indications for Use	The **Arthrex PushLock Suture Anchors (2.9 - 4.5 mm)** are 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, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction, Lateral Epicondylitis repair. Hip: Capsular repair (2.9 x 15.5 - 24 mm only), acetabular labral repair. The **Arthrex PushLock Suture Anchors (2.5 mm)** are intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, and shoulder. Specific indications are listed below: 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 The **Arthrex Short Suture Anchors (2.0 - 2.4 mm)** are intended to be used for suture (soft tissue) fixation to bone in the hip. Specifically, acetabular labral repair. The **Arthrex Self-Punching PushLock Suture Anchors (3.5 mm)** are intended to be used for suture (soft tissue) fixation to bone in the shoulder: Shoulder: Rotator Cuff Repair
Performance Data	To demonstrate product performance and safety, Arthrex has conducted product functionality (accelerated aging), product induced radiation, sterilization validation, biological safety evaluation and temperature study testing comparing the results to the primary predicate device K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; additional predicate devices K063479 Arthrex PushLock, K101679 Arthrex PushLock Anchors, K151092 Arthrex Short Suture Anchors, and K221099 Arthrex Self-Punching PushLock Suture Anchors; and reference device K093912 Arthrex Tibial GraftBolt.

Technological Comparison	The Arthrex PushLock Suture Anchors are substantially equivalent to the predicate devices cleared under the primary predicate device K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; additional predicate devices K063479 Arthrex PushLock, K101679 Arthrex PushLock Anchors, K151092 Arthrex Short Suture Anchors, and K221099 Arthrex Self-Punching PushLock Suture Anchors; and reference device K093912 Arthrex Tibial GraftBolt in which basic design features, intended use, fundamental scientific technology, materials, packaging, and sterility are identical. <u>Indications for Use:</u> • The indications for use for the subject Arthrex PushLock Suture Anchors are equivalent to the primary predicate device K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; and additional predicate devices; K063479 Arthrex PushLock, K101679 Arthrex PushLock Anchors, K151092 Arthrex Short Suture Anchors, and K221099 Arthrex Self-Punching PushLock Suture Anchors. <u>Material:</u> • The Arthrex PushLock Suture Anchors are made from Polyetheretherketone (PEEK) conforming to ASTM F2026 which is equivalent to the material cleared under the primary predicate device K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; and additional predicate devices PushLock Family; K063479 Arthrex PushLock, K101679 Arthrex PushLock Anchors, K151092 Arthrex Short Suture Anchors, K221099 Arthrex Self-Punching PushLock Suture Anchor; and reference device K093912 Arthrex Tibial GraftBolt. <u>Packaging:</u> • The Arthrex PushLock Suture Anchors packaging configurations are equivalent to the packaging configurations cleared under the primary predicate device K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; and additional predicate devices PushLock Family; K063479 Arthrex PushLock,

	K101679 Arthrex PushLock Anchors, K151092 Arthrex Short Suture Anchors, and K221099 Arthrex Self-Punching PushLock Suture Anchors; and reference devices K093912 Arthrex Tibial GraftBolt and K181513 Arthrex PushLock Tenodesis Anchor. Shelf-Life: • The shelf-life of the Arthrex PushLock Suture Anchors is 5-years which is equivalent to the primary predicate device K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; and additional predicate devices K063479 Arthrex PushLock, K101679 Arthrex PushLock Anchors, K151092 Arthrex Short Suture Anchors, K221099 Arthrex Self-Punching PushLock Suture Anchor, and reference device K093912 Arthrex Tibial GraftBolt. MRI Safety: • The MRI Safety of the Arthrex PushLock Suture Anchors is identical to the additional predicate device K221099 Arthrex Self-Punching PushLock Suture Anchors. Sterility: • The Sterility Assurance Level (SAL) of the Arthrex PushLock Suture Anchor is identical to that cleared under the primary predicate device K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; and additional predicate devices K063479 Arthrex PushLock, K101679 Arthrex PushLock Anchors, K151092 Arthrex Short Suture Anchors, K221099 Arthrex Self-Punching PushLock Suture Anchor, and reference device K093912 Arthrex Tibial GraftBolt. The Arthrex PushLock Suture Anchors are substantially equivalent to the predicate devices cleared primary predicate device K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; additional predicate devices K063479 Arthrex PushLock, K101679 Arthrex PushLock Anchors, K151092 Arthrex Short Suture Anchors, and K221099 Arthrex Self-Punching PushLock Suture Anchors; and reference device K093912 Arthrex Tibial GraftBolt

	with minor modifications with no change to the intended use, design, or function. Any differences between the Arthrex PushLock Suture Anchors and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex PushLock Suture Anchors are substantially equivalent to the predicate devices cleared under K061863, K063479, K101679, K151092, K221099, K093912, and K181513 in which the basic design features and intended use are the same. Any differences between the Arthrex PushLock Suture Anchors and the predicate devices are considered minor and do not raise different questions of safety or effectiveness. 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.