



May 28, 2026

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

Re: K253931

Trade/Device Name: Arthrex Bioabsorbable PushLock Suture Anchors
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI
Dated: April 27, 2026
Received: April 27, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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.

K253931

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Please provide the device trade name(s).

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Arthrex Bioabsorbable PushLock Suture Anchors

Please provide your Indications for Use below.

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The Arthrex BioComposite PushLock Suture Anchors (4.5 mm) 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 Repairs, 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 or Radial 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, acetabular labral repair.

The Arthrex Bio-PushLock Suture Anchors (3.5 mm) 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, 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, acetabular labral repair

The Arthrex BioComposite PushLock Suture Anchors (2.5 mm) is intended to be used for suture or tissue

fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and in select maxillofacial applications. Specific indications are listed below:

Skull: Stabilization and fixation of oral cranio-maxillofacial skeletal bone, mandible and maxillofacial bones, Lateral Canthoplasty, Repair of Nasal Vestibular Stenosis, Brow Lift, Temporomandibular Joint (TMJ) reconstruction, soft tissue attachment to the parietal temporal ridge, frontal, zygoma, and periorbital bones of the skull

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 BioComposite PushLock Suture Anchors (2.4, 2.9 and 3.5 mm) are intended to be used for 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, Metatarsal Ligament Repair/ Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Bunionectomy, Digital Tendon Transfers (2.9 x 15.5 mm only)

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

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair

Hip: Acetabular Labral Repair, Capsular Repair (2.9 x 15.5 mm only)

The Arthrex BioComposite Mini Hip PushLock Suture Anchors (2.4 mm) is intended to be used for suture (soft tissue) to bone in the hip. Specifically, Acetabular Labral Repair.

The Arthrex BioComposite 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 Repairs

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](#))

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510(k) Summary

Date Prepared	12/08/2025
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 Bioabsorbable PushLock Suture Anchors
Common Name	Suture Anchor
Product Code	MAI
Classification Name	fastener, fixation, biodegradable, soft tissue
Regulatory Class	II - 21 CFR 888.3030:
Primary Predicate Device	K173240 – Arthrex PushLock
Additional Predicate Devices	K061863 – Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family K063479 – Arthrex 2.5mm PushLock K082810 – Arthrex Bio-Composite Suture Anchors, Expansion of Indications to include Hip K101679 – Arthrex PushLock K201786 – Arthrex Mini Hip PushLock K221099 – Arthrex Self-Punching PushLock Suture Anchor
Reference Device	K251145 – Arthrex PushLock Suture Anchors
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to expand the indications for use for the Arthrex Bioabsorbable PushLock Suture Anchors sterilized using the Arthrex X-ray radiation sterilization process.
Device Description	The Arthrex Bio and BioComposite PushLock Suture Anchor is a two piece “push-in” suture anchor device comprised of a PLLA (Poly(L-lactide)/Polyetheretherketone) or PLLA/ βTCP (TriCalcium Phosphate, 85/15%) anchor body with a polyetheretherketone (PEEK) eyelet pre-loaded on a disposable inserter. The anchor is threaded and range from 2.4 mm to 4.5 mm in diameter and 8 mm to approximately 24 mm in length. The anchor is sold sterile and is single-use. The Arthrex BioComposite Self-Punching PushLock Suture Anchor is a "push-in" suture anchor comprised of a PLLA/

	βTCP (TriCalcium Phosphate, 85/15%) 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 anchor is sold sterile and is single-use.
Indications for Use	The Arthrex BioComposite PushLock Suture Anchors (4.5 mm) 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 Repairs, 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 or Radial 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, acetabular labral repair. The Arthrex Bio-PushLock Suture Anchors (3.5 mm) 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, 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, acetabular labral repair
	The Arthrex BioComposite PushLock Suture Anchors (2.5 mm) is intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and in select maxillofacial applications. Specific indications are listed below: Skull: Stabilization and fixation of oral cranio-maxillofacial skeletal bone, mandible and maxillofacial bones, Lateral Canthoplasty, Repair of Nasal Vestibular Stenosis, Brow Lift, Temporomandibular Joint (TMJ) reconstruction, soft tissue attachment to the parietal temporal ridge, frontal, zygoma, and periorbital bones of the skull 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 BioComposite PushLock Suture Anchors (2.4, 2.9 and 3.5 mm) are intended to be used for 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, Metatarsal Ligament Repair/Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Bunionectomy, Digital Tendon Transfers (2.9 x 15.5 mm only) Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patella Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair Hip: Acetabular Labral Repair, Capsular Repair (2.9 x 15.5 mm only)

	The Arthrex BioComposite Mini Hip PushLock Suture Anchors (2.4 mm) is intended to be used for suture (soft tissue) to bone in the hip. Specifically, Acetabular Labral Repair. The Arthrex BioComposite 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 Repairs
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 K173240 Arthrex PushLock; and additional predicate devices K082810 Arthrex Bio-Composite Suture Anchors, Expansion of Indications to include Hip; K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; K063479 Arthrex PushLock; K101679 Arthrex PushLock Anchors; K201786 Arthrex Mini Hip PushLock and K221099 Arthrex Self-Punching PushLock Suture Anchors.
Technological Comparison	The Arthrex PushLock Suture Anchors are substantially equivalent to the predicate devices cleared under the primary predicate device K173240 Arthrex PushLock; and additional predicate devices K082810 Arthrex Bio-Composite Suture Anchors, Expansion of Indications to include Hip; K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; K063479 Arthrex PushLock; K101679 Arthrex PushLock Anchors; K201786 Arthrex Mini Hip PushLock and K221099 Arthrex Self-Punching PushLock Suture Anchors; and reference device K251145 Arthrex PushLock Suture Anchors 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 Arthrex Bioabsorbable PushLock Suture Anchors are equivalent to the primary predicate device K173240 Arthrex PushLock; and additional predicate devices K082810 Arthrex Bio-Composite Suture Anchors, Expansion of Indications to

include Hip; K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; K063479 Arthrex PushLock; K101679 Arthrex PushLock Anchors; K201786 Arthrex Mini Hip PushLock and K221099 Arthrex Self-Punching PushLock Suture Anchors.

Material:

- The Arthrex Bioabsorbable PushLock Suture Anchors consist of an anchor body made from PLLA (Poly(L-lactide)/Polyetheretherketone) or PLLA/ β TCP (TriCalcium Phosphate, 85/15%) with a polyetheretherketone (PEEK) eyelet which is equivalent to the material cleared under the primary predicate device K173240 Arthrex PushLock; and additional predicate devices K082810 Arthrex Bio-Composite Suture Anchors, Expansion of Indications to include Hip; K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; K063479 Arthrex PushLock; K101679 Arthrex PushLock Anchors; K201786 Arthrex Mini Hip PushLock and K221099 Arthrex Self-Punching PushLock Suture Anchors.

Packaging:

- The Arthrex Bioabsorbable PushLock Suture Anchors packaging configurations are equivalent to the packaging configurations cleared under the additional predicate devices K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; K082810 Arthrex Bio-Composite Suture Anchors, Expansion of Indications to include Hip; and K101679 Arthrex PushLock Anchors.

Shelf-Life:

- The Arthrex Bioabsorbable PushLock Suture Anchors have a 4-year shelf-life which is equivalent to the 4-year shelf-life cleared under the primary predicate device K173240 Arthrex PushLock; and additional predicate devices K201786 Arthrex Mini Hip PushLock and K221099 Arthrex Self-Punching PushLock Suture Anchors.
 - The Arthrex Bioabsorbable PushLock Suture Anchors have a 2-year shelf-life which is equivalent to the 2-year shelf-life cleared under additional predicate devices
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K082810 Arthrex Bio-Composite Suture Anchors, Expansion of Indications to include Hip; K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; K063479 Arthrex PushLock; and K101679 Arthrex PushLock Anchors.

MRI Safety:

- The MRI Safety of the Arthrex PushLock Suture Anchors is identical to the additional predicate device K201786 Arthrex Mini Hip PushLock and 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 K173240 Arthrex PushLock; and additional predicate devices K082810 Arthrex Bio-Composite Suture Anchors, Expansion of Indications to include Hip; K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; K063479 Arthrex PushLock; K101679 Arthrex PushLock Anchors; K201786 Arthrex Mini Hip PushLock and K221099 Arthrex Self-Punching PushLock Suture Anchors; and reference device K251145 Arthrex PushLock Suture Anchors.

The Arthrex Bioabsorbable PushLock Suture Anchors are substantially equivalent to the predicate devices cleared primary predicate device K173240 Arthrex PushLock; and additional predicate devices K082810 Arthrex Bio-Composite Suture Anchors, Expansion of Indications to include Hip; K061863 Arthrex Corkscrew Suture Anchor, Tak, and PushLock Family; K063479 Arthrex PushLock; K101679 Arthrex PushLock Anchors; K201786 Arthrex Mini Hip PushLock and K221099 Arthrex Self-Punching PushLock Suture Anchors; and reference device K251145 Arthrex PushLock Suture Anchors with minor modifications with no change to the intended use, design, or function. Any differences between the Arthrex Bioabsorbable PushLock Suture Anchors and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.

Conclusion	The Arthrex Bioabsorbable PushLock Suture Anchors are substantially equivalent to the predicate devices cleared under K173240, K082810, K061863, K063479, K101679, K201786, K221099 and K251145 in which the basic design features and intended use are the same. Any differences between the Arthrex Bioabsorbable 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.
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