



August 7, 2026

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

Re: K262357

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: July 10, 2026
Received: July 10, 2026

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 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.

K262357

?

Please provide the device trade name(s).

?

Arthrex Bioabsorbable PushLock Suture Anchors

Please provide your Indications for Use below.

?

The Arthrex BioComposite PushLock Suture Anchors (2.5 mm) is intended to be used for suture (soft 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, Triangular Fibrocartilage Complex (TFCC) Repair

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

Please select the types of uses.

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

?

510(k) Summary

Date Prepared	07/09/2026
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Alex Underberg Title: Regulatory Affairs Specialist, Senior Email: Alex.Underberg@Arthrex.com
Trade Name	Arthrex Bioabsorbable PushLock Suture Anchors
Common Name	Fastener, Fixation, Biodegradable, Soft-Tissue
Product Code	MAI
Classification Name	21 CFR 888.3030: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class	Class II
Primary Predicate Device	K253931: Arthrex Bioabsorbable PushLock Suture Anchors
Additional Predicate Devices	K132079: Smith & Nephew TFCC Fast-Fix Kit
Purpose of Submission	This Special 510(k) premarket notification is submitted to expand the indications for the subject Arthrex Bioabsorbable PushLock Suture Anchors to include TFCC Repair.
Device Description	The Arthrex BioComposite PushLock Suture Anchor is a two piece "push-in" suture anchor device comprised of PLLA/ β TCP (TriCalcium Phosphate, 85/15%) anchor body with a polyetheretherketone (PEEK) eyelet pre-loaded on a disposable inserter.
Indications for Use	The Arthrex BioComposite PushLock Suture Anchors (2.5 mm) is intended to be used for suture (soft 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 perioorbital 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, Triangular Fibrocartilage Complex (TFCC) Repair 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
Performance Data	Arthrex completed verification and validation testing to confirm that the subject devices meet the defined acceptance criteria. ASTM F3690 testing was completed. Per the verification and validation testing that was completed, the subject devices meet all the established acceptance criteria.
Technological Comparison	The subject and primary predicate devices are identical devices. The additional predicate, rather than being a suture anchor, contains two non-absorbable polymer implants, pre-tied with #2-0 non-absorbable suture. The subject and predicate devices are all preloaded on inserters. 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 subject devices are substantially equivalent to the predicate devices. Any differences between the subject devices 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 devices are substantially equivalent to the currently marketed predicate devices.