June 4, 2024

Arthrex, Inc.
Emmarie Halteman
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K233971
Trade/Device Name: Arthrex AlloSync PushLock Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, HWC
Dated: May 8, 2024
Received: May 9, 2024

Dear Emmarie Halteman:

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.

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,

Jesse Muir -S
Digitally signed by Jesse Muir -S
Date: 2024.06.04 15:32:02 -04'00'

Jesse Muir, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233971

Device Name
Arthrex AlloSync™ PushLock® Suture Anchor

Indications for Use *(Describe)*
The Arthrex AlloSync™ PushLock® suture anchors are intended to be used for suture (soft tissue) fixation to bone in the shoulder in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, Superior Labrum from Anterior to Posterior (SLAP) Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral 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.

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510(k) Summary

Date Prepared	May 22, 2024
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Emmarie Halteman Title: Senior Regulatory Affairs Specialist Phone: 1-239-643-5553 ext. 74232 Email: emmarie.halteman@arthrex.com
Trade Name	Arthrex AlloSync™ PushLock® Suture Anchor
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Product Code	MAI – Fastener, Fixation, Biodegradable, Soft Tissue HWC – Screw, Fixation, Bone
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories; Fastener, Fixation, Biodegradable, Soft Tissue 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	K063479: Arthrex 2.5mm PushLock
Reference Device	K070347: Allofix Push-In Anchor
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex AlloSync™ PushLock® Suture Anchor
Device Description	The Arthrex AlloSync™ PushLock® Suture Anchor is a two-component suture anchor comprised of a hollow anchor body manufactured from human cortical bone, a Polyetheretherketone (PEEK) eyelet, and a disposable driver inserter. The anchor will be offered in a 2.9mm diameter and 12.5mm in total length (anchor + eyelet). The anchor is sold sterile, single-use.
Indications for Use	The Arthrex AlloSync™ PushLock® suture anchors are intended to be used for suture (soft tissue) fixation to bone in the shoulder in the following procedures: **Shoulder:** Rotator Cuff Repair, Bankart Repair, Superior Labrum from Anterior to Posterior (SLAP) Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Performance Data	The submitted mechanical test data, pull-out, insertion, and degradation, demonstrates that the Arthrex AlloSync™ PushLock® Suture Anchor results in statistically equivalent strength to the predicate device Arthrex 2.5mm PushLock (K063479).

	Bacterial Endotoxin Testing (BET) was performed on the Arthrex AlloSync™ PushLock® Suture Anchor utilizing the Kinetic Turbidimetric limulus amebocyte lysate (LAL) method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820. The testing conducted demonstrates that the Arthrex AlloSync™ PushLock® Suture Anchor meets pyrogen limit specifications. All donors have been screened and tissues recovered, processed, stored, tested, and distributed in accordance with current U.S. federal regulations as promulgated in 21 CFR 1270 and 1271, current Standards for Tissue Banking set forth by the American Association of Tissue Banks (AATB) and international laws and regulations as required. This allograft was deemed suitable for implantation by LifeNet Health. A physician medical director evaluated the following donor variables to determine donor suitability: infectious disease test results, current donor medical history, behavioral risk assessment interview, physical assessment, relevant medical records, including previous medical history, laboratory test results, and autopsy or coroner reports (if performed). All donors are tested for relevant infectious diseases. Testing is performed by laboratories that are registered with the U.S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR 493. Test methods that are FDA-licensed, approved, or cleared for donor screening are used as available. The following test criteria were met for the donor of this allograft bio-implant: Hepatitis B virus (HBV) surface antigen, HBV core antibody, Hepatitis C virus (HCV) antibody, HIV-1/12 antibody, Syphilis, HIV-1 NAT, HCT NAT, and HBV NAT. Cytotoxicity, Sensitization, Irritation, Genotoxicity, Acute Systemic Toxicity, Implantation, Material Mediated Pyrogenicity, and Material Chemical Characterization was conducted on the Arthrex AlloSync™ PushLock® Suture Anchor in accordance with ISO 10993-1:2018 and deemed biocompatible when used as intended.
Technological Comparison	Compared to the predicate device Arthrex 2.5mm PushLock (K063479), the proposed Arthrex AlloSync™ PushLock® Suture Anchor has the same intended use/indications for the shoulder, fundamental scientific technology, sterility, and shelf-life. The proposed Arthrex AlloSync™ PushLock® Suture Anchor's anchor body is made of human cortical bone; whereas the primary predicate device Arthrex 2.5mm PushLock is made of Poly (l-lactide) (PLLA). However, the anchor body cleared under reference

	device Allofix Push-In Anchor (K070347) is made of human allograft bone and they both comply with all requirements in 21 CFR 1271 to reduce the risk of the introduction, transmission, and spread of communicable diseases by human cells, tissues, and cellular and tissue-based products (HCT/Ps). Any differences between the proposed device and the predicate device are considered minor and do not raise new or different questions concerning safety or effectiveness.
Conclusion	The Arthrex AlloSync™ PushLock® Suture Anchor is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise different questions concerning 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 device.