May 13, 2022

Arthrex Inc.
Kelsey Roberts
Sr. Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K221099
Trade/Device Name: Arthrex Self-Punching 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, MBI
Dated: April 13, 2022
Received: April 14, 2022

Dear Ms. Roberts:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For:

Laura C. Rose, 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

Arthrex Inc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221099

Device Name

Arthrex Self-Punching PushLock® Suture Anchors

Indications for Use *(Describe)*

The Arthrex self-punching PushLock suture anchors are intended to be used for suture (soft tissue) fixation to bone in the shoulder:

• Shoulder: Rotator Cuff Repair

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
PRAStaff@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

510(k)	K221099
Date Prepared	May 13, 2022
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Kelsey Roberts Sr. Regulatory Affairs Specialist 1-239-598-4302, ext. 72257 Kelsey.Roberts@arthrex.com
Name of Device	Arthrex Self-Punching PushLock® Suture Anchor
Common Name	Smooth or threaded metallic bone fixation fastener
Product Code	MAI – Fastener, Fixation, Biodegradable, Soft Tissue HWC – Screw, Fixation, Bone MBI – Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener.
Regulatory Classification	II
Predicate Device	K101679: Arthrex PushLock Anchors
Reference Device	K061863: Arthrex Corkscrew, Corkscrew FT, Bio-Corkscrew, and Bio-Corkscrew FT Suture Anchors K082810: Bio-Composite Suture Anchors, Expansion of Indications to include Hip K173240: Arthrex PushLock K193503: Arthrex SwiveLock Suture Anchor
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the Arthrex Self-Punching PushLock Suture Anchors as a line extension to the Arthrex PushLock Suture Anchors cleared via K101679.
Device Description	The Arthrex Self-Punching PushLock Anchor is a push-in, fully threaded barbed suture anchor comprised of a PEEK Optima eyelet and a hollow anchor body pre-assembled on a disposable inserter. The anchor body is made of either PLLA/βTCP or PEEK Optima. The Arthrex Self-Punching PushLock Anchor is intended to be used for suture (soft tissue) fixation to bone in the shoulder.
Comparison Summary of Technological Characteristics and Modifications Proposed	The proposed device has the same technological characteristics (anchor design, material, sterilization method, and biocompatibility profile) as the predicate device cleared under K101679. The proposed device modification consists of a PEEK self-punching eyelet; whereas the eyelet of the predicate device cleared under K101679 was non-self-punching. The Arthrex Self-Punching PushLock Anchors are substantially equivalent to the predicate device in which the design features and intended uses are the same. Any differences between the proposed device and the predicate devices are considered minor and do not result in new or different questions concerning safety or effectiveness.
Indications for Use	The Arthrex self-punching PushLock suture anchors are intended to be used for suture (soft tissue) fixation to bone in the shoulder:

	Shoulder: Rotator Cuff Repair
Performance Data	Ultimate load testing and insertion testing was performed on the subject device and compared to the predicate device cleared under K101679 to demonstrate that the modifications do not negatively impact mechanical strength. The shelf life of the Biocomposite Arthrex Self-Punching PushLock suture anchor is 4 years. The same methods and protocols were used which were reviewed by FDA in K173240. The Arthrex Self-Punching PushLock suture anchors are MR safe as they are nonmetallic, nonconducting materials that do not contain ferromagnetic materials or any other metallic markers that can interfere with magnetic resonance imaging (MRI). There are no concerns with the performance of the devices in an MRI environment. These devices are labeled MR safe per ASTM F2503. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Conclusion	The Arthrex Self-Punching Pushlock Suture Anchors are substantially equivalent to the predicate devices in which the basic design features and intended use are the same. Any differences between the proposed device 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 proposed device is substantially equivalent to the currently marketed predicate device.