April 19, 2021

Arthrex Inc.
Kelsey Roberts
Regulatory Affairs Specialist II
1370 Creekside Boulevard
Naples, Florida 34108

Re: K203495/S001
Trade/Device Name: Arthrex SwiveLock 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, MBI
Dated: March 15, 2021
Received: March 16, 2021

Dear Kelsey 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,

Laura C. Rose -S

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

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)*
K203495

Device Name
Arthrex SwiveLock Anchor

Indications for Use *(Describe)*
The Arthrex SwiveLock Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in skeletally mature pediatric and adult patients for the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis Capsulolabral Reconstruction, Acromio-Clavicular Separation Repair, Deltoid Repair,
Capsular Shift or Capsulo labral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament/Tendon Repair, and Bunionectomy

Knee: Anterior Cruciate Ligament Repair (4.75- 5.5 SwiveLock Only), Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Quadriceps Tendon Repair (4.75 SwiveLock C Only), Meniscal Root Repair (4.75 SwiveLock C Only), Secondary or adjunct fixation for ACL/PCL reconstruction or repair (4.75-5.5 SwiveLock only), MPFL Repair/Reconstruction(3.9 SwiveLock Only)

Hand/Wrist: Scapholunate Ligament Reconstruction and Ulnar/Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction, and Lateral Epicondylitis repair

Hip: Capsular Repair, Acetabular labral repair, Gluteus Medius Repair (4.75 – 5.5 mm PEEK SwiveLock suture anchors only), and Proximal Hamstring Repair (4.75 – 5.5 mm PEEK SwiveLock suture anchors only).

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	March 10, 2021
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Kelsey N. Roberts Regulatory Affairs Associate Specialist 1-239-643-5553, ext. 72257 Kelsey.Roberts@arthrex.com
Name of Device	Arthrex SwiveLock Suture Anchor
Common Name	Suture Anchor
Product Code(s)	MAI MBI
Classification Name(s)	21 CFR 888.3040: Smooth or threaded metallic bone fastener 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	II
Predicate Device(s)	K191226: Arthrex SwiveLock Suture Anchor K201749: Arthrex SwiveLock Anchor
Reference Device(s)	K173240: Arthrex PushLock K173845: Arthrex SwiveLock K190728 - Arthrex SwiveLock Anchors K192441- Arthrex SwiveLock Anchors K143745 – Arthrex Corkscrew and SwiveLock Suture Anchors
Purpose of Submission	This premarket notification is submitted to obtain pediatric indications for the Arthrex SwiveLock Suture Anchors cleared under K191226 and K201749.
Device Description	The Arthrex SwiveLock Anchor is a sterile two-component suture anchor comprised of an eyelet and a hollow anchor body. The Arthrex SwiveLock Anchor is pre-mounted on a driver with an anchor body and eyelet physically separated on the driver shaft. Arthrex 510(k) cleared suture may also be provided with the device.
Comparison Summary of Technological Characteristics and Modifications Proposed	The proposed devices have the same technological characteristics (device design, sterilization, and biocompatibility). The proposed device modification consists of the additional patient population including pediatric patients in skeletally mature bone and an extended shelf life. The Arthrex SwiveLock Suture Anchors are substantially equivalent to the predicate device in which the design features and intended uses are the same. Any differences between the Arthrex proposed device and the predicate device are considered minor and do not result in new or different questions of safety or effectiveness
Indications for Use	The Arthrex SwiveLock Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in skeletally mature pediatric and adult patients for the following procedures: Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis Capsulolabral Reconstruction, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulo labral Reconstruction. Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament/Tendon Repair, and Bunionectomy Knee: Anterior Cruciate Ligament Repair (4.75- 5.5 SwiveLock Only), Medial Collateral

	Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Quadriceps Tendon Repair (4.75 SwiveLock C Only), Meniscal Root Repair (4.75 SwiveLock C Only), Secondary or adjunct fixation for ACL/PCL reconstruction or repair (4.75-5.5 SwiveLock only), MPFL Repair/Reconstruction(3.9 SwiveLock Only) Hand/Wrist: Scapholunate Ligament Reconstruction and Ulnar/Radial Collateral Ligament Reconstruction Elbow: Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction, and Lateral Epicondylitis repair Hip: Capsular Repair, Acetabular labral repair, Gluteus Medius Repair (4.75 – 5.5 mm PEEK SwiveLock suture anchors only), and Proximal Hamstring Repair (4.75 – 5.5 mm PEEK SwiveLock suture anchors only).
Performance Data	Ultimate load testing and cyclic displacement was performed on the subject device and compared to the predicate device to demonstrate that the modifications do not negatively impact mechanical strength. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Clinical Literature	Clinical literature was provided on the subject devices involving the proposed patient population of skeletally mature pediatric patients. The reviewed literature shows the device is effective when used in the proposed patient population with skeletally mature bone.
Real World Data/Evidence	Real World Data/Evidence is provided from the Surgical Outcomes System registry. Based on the patient outcomes, there are no statistical differences in patients less 22 years of age versus patients greater than 22 years of age.
Conclusion	The Arthrex SwiveLock 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 Arthrex proposed device and the predicate device are considered minor and do not result in new or 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 device.