March 17, 2023

Arthrex, Inc.
Stacy Valdez, M.S.
Sr. Regulatory Affairs Specialist
370 Creekside Boulevard
Naples, Florida 34113

Re: K230435
Trade/Device Name: Arthrex 3.9 mm 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, HWC
Dated: February 14, 2023
Received: February 17, 2023

Dear Ms. Valdez:

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,

Sara S. Thompson -S

For

Laurence D. Coyne, Ph.D.
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.*

Submission Number *(if known)*

K230435

Device Name

Arthrex 3.9 mm 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: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, and MPFL Repair Reconstruction

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 and Acetabular labral 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.

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# 510(k) Summary

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| ***Date Prepared*** | February 14, 2023 |
| ***Submitter*** | Arthrex Inc.<br>1370 Creekside Boulevard<br>Naples, FL 34108-1945 |
| ***Contact Person*** | Stacy Valdez<br>Senior Regulatory Affairs Specialist<br>1-239-643-5553, ext. 72010<br>stacy.valdez@arthrex.com |
| ***Name of Device*** | Arthrex 3.9 mm SwiveLock Anchor |
| ***Common Name*** | Suture Anchor |
| ***Product Code*** | MAI, HWC |
| ***Classification Name*** | 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories (Primary)<br>21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener |
| ***Regulatory Class*** | II |
| ***Primary Predicate Device*** | K192532: Arthrex SwiveLock Anchor |
| ***Additional Predicate Device*** | K203495: Arthrex SwiveLock Anchor |
| ***Purpose of Submission*** | This Special 510(k) premarket notification is submitted to obtain clearance for the Arthrex 3.9 mm SwiveLock Anchor |
| ***Device Description*** | The proposed Arthrex 3.9 mm SwiveLock Anchor is a sterile two-component suture anchor comprised of an eyelet and a hollow anchor body. The Arthrex 3.9 mm SwiveLock Anchor is pre-mounted on a driver with the anchor body and eyelet physically separated on the driver shaft. The Arthrex 3.9 mm SwiveLock Anchor can be used with Arthrex 510(k) cleared suture. |
| ***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:<br><br>**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.<br><br>**Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament/Tendon Repair, and Bunionectomy.<br><br>**Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, and MPFL Repair/Reconstruction.<br><br>**Hand/Wrist:** Scapholunate Ligament Reconstruction and Ulnar/Radial Collateral Ligament Reconstruction.<br><br>**Elbow:** Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction, and Lateral Epicondylitis Repair.<br><br>**Hip:** Capsular Repair, Acetabular labral repair. |

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| ***Performance Data*** | Packaging validation and 5-year accelerated aging shelf-life testing was performed to demonstrate that the packaging configurations are capable of maintaining and protecting the product and sterility of the device throughout the shipping and handling environment. The packaging configuration met all the packaging testing acceptance criteria in conformance to ISO 11607 and applicable standards.<br><br>Bacterial Endotoxins Test (BET) was performed on the representative samples utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14 to demonstrate that the proposed device meets pyrogen limit specifications. |
| ***Technological Comparison*** | The Arthrex 3.9 mm SwiveLock Anchor is substantially equivalent to the predicate devices cleared under K192532 and K203495 in which the overall design, intended use, indications, materials, design, sterility, shelf-life, surgical technique, and MRI safety labeling is identical.<br><br>The Arthrex 3.9 mm SwiveLock Anchor will be packaged in inner PETG blister tray with Tyvek lid and outer poly/Tyvek pouch. The predicate devices cleared under K192532 and K203495 are packaged in an inner PETG blister tray with Tyvek lid and outer foil pouch.<br><br>Any differences between the Arthrex 3.9 mm SwiveLock Anchor and the predicate devices are considered minor and do not raise different questions of safety or effectiveness. |
| ***Conclusion*** | The Arthrex 3.9 mm SwiveLock Anchor is substantially equivalent to the predicate devices in which the basic design features and intended use are the same. Any differences between the proposed Arthrex 3.9 mm SwiveLock Anchor and the predicate devices 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 device. |