March 14, 2025

Arthrex, Inc.
Ruth Segall
Regulatory Affairs Specialist II
1370 Creekside Boulevard
Naples, Florida 34108

Re: K250526
Trade/Device Name: Arthrex 4.75 mm Double Loaded Knotless Corkscrew 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, MBI
Dated: February 21, 2025
Received: February 24, 2025

Dear Ms. Segall:

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.

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, MS
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.

Submission Number *(if known)*

K250526

Device Name

Arthrex 4.75 mm Double Loaded Knotless Corkscrew Suture Anchor

Indications for Use *(Describe)*

The Arthrex 4.75 mm Double Loaded Knotless Corkscrew Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder. Specifically, rotator cuff repairs.

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	03/14/2025
510(k) Number	K250526
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Ruth Segall Title: Regulatory Affairs Specialist II Phone: 239-598-4302 x 71764 Email: Ruth.Segall@arthrex.com
Trade Name	Arthrex 4.75mm Double Loaded Knotless Corkscrew® Suture Anchor
Common Name	Suture Anchor
Product Code	MAI, MBI
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	Class II
Primary Predicate Device	K173788: Arthrex Corkscrew FT
Additional Predicate Devices	N/A
Reference Devices	K193157: Arthrex 3.9 mm Corkscrew Suture Anchor K230433: Arthrex Double Loaded Knotless FiberTak® Suture Anchor
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the Arthrex 4.75 mm Double Loaded Knotless Corkscrew Suture Anchor as a line extension to the Arthrex Corkscrew Suture Anchors cleared via K173788.
Device Description	The Arthrex 4.75 mm Double Loaded Knotless Corkscrew Suture Anchor is a fully threaded knotless suture anchor that is pre-loaded on a disposable inserter with Arthrex sutures. The anchor may be manufactured from either BioComposite (PLLA/βTCP TriCalcium Phosphate) or PEEK (Polyether-ether-ketone)

	The Arthrex 4.75 mm Double Loaded Knotless Corkscrew Suture Anchor is provided sterile (Ethylene Oxide), single-use, and is packaged in a single-pack or 5-pack.
Indications for Use	The Arthrex 4.75 mm Double Loaded Knotless Corkscrew Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder. Specifically, rotator cuff repairs.
Performance Data	Tensile (pull-out) testing was conducted on the proposed Arthrex 4.75 mm Doubled Loaded Knotless Corkscrew Suture Anchor submitted in this Special 510(k). The test data demonstrates that the proposed device performs statistically equivalent to the predicate device for the intended indications for use. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Technological and Predicate Comparison	The Arthrex 4.75 mm Double Loaded Knotless Corkscrew Suture Anchor are a line extension to the predicate device K173788. The indications for use for the subject device are a subset of the indications of the predicate device. The proposed and predicate devices have identical basic design, indications for use, intended use, packaging, shelf-life, biocompatibility profile, manufacturing, and sterilization processes. In comparison to the predicate device, the proposed modifications include minor modifications to the method of fixation of the suture to the anchor, creating a closed loop within the anchor body, and the pre-loaded suture. Any differences between the proposed and predicate devices are considered minor and do not raise any questions concerning safety or effectiveness.
Conclusion	The Arthrex 4.75 mm Double Loaded Knotless Corkscrew Suture Anchor is substantially equivalent to the predicate devices in which the basic design features and intended use are identical. The proposed device is indicated for a subset of the indications for use of the

	predicate device. 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.