December 30, 2025

Arthrex, Inc.
Stacy Valdez
Principal Regulatory Affairs Specialist
1370 Creekside Blvd.
Naples, Florida 34108

Re: K253895
Trade/Device Name: Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 4, 2025
Received: December 4, 2025

Dear Stacy 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 (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, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253895

Please provide the device trade name(s).

Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm

Please provide your Indications for Use below.

The Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm is intended to be used for suture or tissue fixation in the foot/ankle and hand/wrist. Specific indications for use are listed below:

• Hand/Wrist: Repair of Collateral Ligaments, Repair of Flexor and Extensor Tendous at the PIP, DIP and MCP joints for all digits and Carpometacarpal Joint Arthroplasty (basal thumb joint arthroplasty)
• Foot/Ankle: Lateral Stabilization, Medial Stabilization, Metatarsal Ligament Repair, Hallux Valgus Reconstruction

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Date Prepared	12/04/2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Stacy Valdez Title: Principal Regulatory Affairs Specialist Phone: 1-239-643-5553, ext. 72010 Email: stacy.valdez@arthrex.com
Trade Name	Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm
Common Name	Fastener, Fixation, Nondegradable, Soft Tissue
Product Code	MBI
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Primary Predicate Device	K150648: Arthrex DX SwiveLock with Forked Eyelet 3.5 x 8.5 mm
Reference Device	K230435: Arthrex 3.9 mm SwiveLock Anchor
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm as a line extension of the Arthrex SwiveLock Suture Anchors cleared via K150648.
Device Description	The proposed Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm is a knotless, two-component suture anchor consisting of a fully threaded and vented anchor body and a closed eyelet. The anchor and eyelet are manufactured from polyetheretherketone (PEEK Optima per ASTM F2026). The anchor and eyelet are preassembled on a disposable inserter with a suture threader. Arthrex recommends the use of the Arthrex 1.3 mm SutureTape (sold separately) previously cleared within Arthrex SutureTape (K193575). The proposed device is offered sterile, single-use, and is packaged in a single-pack (one per box).
Indications for Use	The Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm is intended to be used for suture or tissue fixation in the foot/ankle and hand/wrist. Specific indications for use are listed below: • Hand/Wrist: Repair of Collateral Ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits and Carpometacarpal Joint Arthroplasty (basal thumb joint arthroplasty) • Foot/Ankle: Lateral Stabilization, Medial Stabilization, Metatarsal Ligament Repair, Hallux Valgus Reconstruction
Performance Data	To demonstrate product performance, Arthrex has conducted cyclic pull-out testing and Failure Torque/Insertion Torque Testing on the proposed Arthrex SwiveLock Anchor, 3.5 x 10 mm

	comparing the results to the Arthrex SwiveLock SL with Forked Eyelet 3.5 x 8.5 mm (K150648) in accordance with ASTM F3690-24 Standard Test Method for Evaluating Suture Anchor Insertion and Pull Displacement Resistance and well-established methods reviewed and accepted by FDA in predicate device Arthrex DX SwiveLock SL with Forked Eyelet 3.5 x 8.5 mm (K150648). Furthermore, Arthrex has completed packaging validation and 5-year real-time aging shelf-life testing to demonstrate that the packaging configuration is capable of maintaining and protecting the product and sterility (EtO sterilized) of the device throughout the shipping and handling environment. Testing was performed using the same test methods submitted and cleared under Arthrex 3.9 mm SwiveLock Anchor (K230435) and/or in accordance with FDA recognized standards. The packaging configuration met all the packaging testing acceptance criteria in conformance to ISO 11607 and applicable standards. Assessment of the physical product attributes including product, design, size, and materials has determined that the Arthrex SwiveLock Anchor, 3.5 x 10 mm does not introduce additional risks or concerns regarding sterilization and shelf-life.

Technological Comparison	Compared to the predicate device Arthrex DX SwiveLock SL with Forked Eyelet 3.5 x 8.5 mm (K150648), the proposed Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm has the same intended use, basic design features, fundamental scientific technology, material, anchor configuration, principle of operation, anchor diameter, sterility, and shelf-life.
	
	The differences between the proposed Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm and the predicate device Arthrex DX SwiveLock SL with Forked Eyelet 3.5 x 8.5 mm (K150648) are as follows:
	• <u>Principle of Operation:</u>
	  ○ The proposed Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm will have a different pilot hole (drill bit) diameter compared to the predicate device Arthrex DX SwiveLock SL with Forked Eyelet 3.5 x 8.5 mm (K150648).
	• <u>Anchor and Eyelet:</u>
	  ○ The total length (anchor and eyelet) of the proposed Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm is longer than the predicate device Arthrex DX SwiveLock SL with Forked Eyelet 3.5 x 8.5 mm (K150648). However, the proposed anchor length falls within the length range

	cleared under the predicate devices within K150648. ○ The proposed Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm will be offered as vented; whereas the predicate device Arthrex DX SwiveLock with Forked Eyelet 3.5 x 8.5 mm (K150648) is non-vented. However, the vented design was previously cleared under the predicate device K150648 (Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5 mm). ○ The proposed Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm will have a closed eyelet; whereas the predicate device Arthrex DX SwiveLock SL with Forked Eyelet 3.5 x 8.5 mm (K150648) has an open (forked) eyelet. However, the closed eyelet design was previously cleared under the predicate device K150648 (Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5 mm). • <u>Arthrex Suture:</u> ○ The proposed Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm will be used with existing Arthrex 1.3 mm SutureTape (sold separately) previously cleared within Arthrex SutureTape (K193575), whereas the predicate device Arthrex DX SwiveLock SL with Forked Eyelet 3.5 x 8.5 mm (K150648) was cleared using existing Arthrex Suture (Size #4-0 to 4 mm) previously cleared under K1010673 (Arthrex FiberWire), K012923 (Arthrex FiberWire USP Size 5 Suture), K041589 (Arthrex FiberWire), K041553 (Arthrex FiberWire and FiberTape) and K122374 (Arthrex Suture). • <u>Packaging Configuration:</u> ○ The proposed Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm will be packaged in a double PETG blister tray with Tyvek lidding inside a carton; whereas the predicate device Arthrex SwiveLock SL with Forked Eyelet 3.5 x 8.5 mm (K150648; AR-8978P) is packaged within a double poly/Tyvek pouch inside a carton. The double PETG blister tray with Tyvek lidding is an existing configurated used on Arthrex anchors (PEEK) cleared within Arthrex PushLock Tenodesis Anchor (K181513). • <u>MRI Safety:</u> ○ The proposed device will be labeled as MR Safe; whereas the predicate device Arthrex DX

	SwiveLock SL with Forked Eyelet 3.5 x 8.5 mm (K150648) was not evaluated for MRI. Based on the intended use, fundamental scientific technology, and the data provided in this Special 510(k), Arthrex has determined that the proposed Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm is substantially equivalent to the predicate device Arthrex DX SwiveLock SL with Forked Eyelet 3.5 x 8.5 mm (K150648). Any differences between the proposed and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.
Conclusion	The Arthrex SwiveLock Suture Anchor, 3.5 x 10 mm is substantially equivalent to the predicate devices cleared under K150648 in which the basic design features and intended use are the same. 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 devices.