September 1, 2023

Arthrex Inc.
Alex Underberg
Regulatory Affairs Specialist, Senior
1370 Creekside Boulevard
Naples, Florida 34108

Re: K232340
Trade/Device Name: Arthrex 2.4mm Knotless Hip SutureTak® Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, HWC, GAT
Dated: August 2, 2023
Received: August 4, 2023

Dear Alex Underberg:

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

Jesse Muir, 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)*
K232340

Device Name

Arthrex 2.4 mm Knotless Hip SutureTak® Suture Anchor

Indications for Use *(Describe)*

The Arthrex 2.4 mm Knotless Hip SutureTak® Suture Anchor is intended to be used for suture (soft tissue) fixation to bone in the hip. Specifically, 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.

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510(k) Summary

Date Prepared	September 1st, 2023
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Alex Underberg Title: Regulatory Affairs Specialist, Senior Email: Alex.Underberg@Arthrex.com
Trade Name	Arthrex 2.4 mm Knotless Hip SutureTak® Suture Anchor
Common Name	Fastener, Fixation, Nondegradable, Soft Tissue
FDA Product Code	MBI (Primary)
	HWC
	GAT
Classification Name	21 CFR 888.3040: Fastener, Fixation, Nondegradable, Soft Tissue (Primary)
	21 CFR 888.3040: Smooth or Threaded Metallic Bone Fixation Fastener
	21 CFR 878.5000: Nonabsorbable Poly(Ethylene terephthalate) Surgical Suture
Regulatory Class	Class II
Primary Predicate Device	Knotless SutureTak® Suture Anchor (K120155, S.E. 02/17/2012)
Reference Devices	Arthrex Short Suture Anchor (K151092, S.E. 02/23/2016)
Purpose of Submission	This Special 510(k) premarket notification is being submitted to obtain clearance for new Arthrex Knotless Hip SutureTak® Suture Anchors as a line extension to previously cleared Arthrex Knotless SutureTak® Suture Anchors cleared within K120155, S.E. 02/17/2012.
Device Description	The Arthrex Knotless Hip SutureTak® Suture Anchor is a non-absorbable, “tap-in” suture anchor with a barbed profile and a proximally placed external suture eyelet. The anchors are preloaded with Arthrex Suture and are offered preassembled on an inserter. The device is single-use.

Indications for Use	The Arthrex 2.4 mm Knotless Hip SutureTak® Suture Anchor is intended to be used for suture (soft tissue) fixation to bone in the hip. Specifically, acetabular labral repair.
Performance Data	Ultimate load testing was performed on the subject device to demonstrate that the minor modifications to the predicate devices does not negatively impact mechanical strength. Bacterial endotoxin adoption, which met the requirements of <20 EU/device of ST72 Bacterial Endotoxin Tests.
Technological Comparison	The subject, predicate and reference devices are all intended to be used for soft tissue fixation to bone in the hip, including acetabular labral repair, are all manufactured from identical materials, are all anchors and suture preloaded on an inserter, and are all sterile, single-use devices. The subject device and predicate device both utilize knotless fixation and utilize a similar internal mechanism to provide strength to the knotless fixation. As described within the device description section of this submission, the reference device is a similar device; however, it does not utilize knotless fixation whereas both the subject and predicate utilize knotless fixation.
Conclusion	The Arthrex 2.4 mm Knotless Hip SutureTak® Suture Anchor is substantially equivalent to the predicate devices in which the design features, intended use, and surgical technique are the same. Any differences between the subject and the predicate devices do not raise different questions concerning safety and 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 devices.