February 2, 2023

Arthrex Inc.
Erikka Edwardsen
Regulatory Affairs Principal Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K223284
Trade/Device Name: SutureLoc™ Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 23, 2022
Received: December 28, 2022

Dear Ms. Edwardsen:

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

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)*
K223284

Device Name
SutureLoc™ Implant

Indications for Use *(Describe)*
The Arthrex SutureLoc™ Implant is intended to be used for suture (soft-tissue) fixation to bone in the knee for meniscal root 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	December 23, 2022
510(k) Number	K223284
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Erikka Edwardsen Regulatory Affairs Principal Specialist 1-239-643-5553, ext. 70422 rikka.edwardsen@arthrex.com
Name of Device	SutureLoc™ Implant
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
Predicate Device	K173845 Arthrex SwiveLock® Anchors
Reference Device	K203268 Arthrex Knotless FiberTak®
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the new Arthrex SutureLoc™ Implant.
Device Description	The SutureLoc™ Implant is a suture construct comprised of a polyester sheath with multiple sutures assembled through the sheath.
Indications for Use	The Arthrex SutureLoc™ Implant is intended to be used for suture (soft-tissue) fixation to bone in the knee for meniscal root repair.
Summary of Technological Characteristics	The proposed device has the same intended use and fundamental technology as the predicate and reference devices. The subject device is comprised of multiple sutures manufactured using the same materials as the Knotless FiberTak® (K203268) device. The primary differences include the stitching suture and use of an accessory device to pull the anchor into the bone.
Performance Data	Ultimate load testing and cyclic displacement was performed on the subject device to demonstrate that the differences do not negatively impact mechanical strength. Bacterial endotoxin per USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications. Packaging testing was conducted to demonstrate shelf-life and confirm the packaging design provides a protective sterile barrier and protects the integrity of the products post sterilization during shipping and handling.
Conclusion	The Arthrex SutureLoc™ Implant is substantially equivalent to the predicate devices in which the basic design features, intended use and surgical technique are the same. Any differences between the subject device and the predicate devices do not raised 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.