September 14, 2022

Arthrex, Inc
Kelsey N. Roberts
Sr. Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K222078
Trade/Device Name: Arthrex SoftStitch
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: July 13, 2022
Received: July 14, 2022

Dear Kelsey N. Roberts:

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,

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)*
K222078

Device Name

Arthrex SoftStitch

Indications for Use *(Describe)*

The Arthrex SoftStitch is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including the repair of meniscal tears and fixation of prosthetic or biologic material to soft tissues in minimally invasive and open surgical procedures such as 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.

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510(k) Summary

Date Prepared	September 1, 2022
510(k) Number	K222078
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Kelsey N. Roberts Sr. Regulatory Affairs Specialist 1-239-643-5553, ext. 72257 Kelsey.Roberts@arthrex.com
Name of Device	Arthrex SoftStitch
Common Name	Fastener, fixation, nondegradable soft tissue
Product Code	GAT
Classification Name	21 CFR 878.5000 – Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class	II
Primary Predicate Device	K190707: Arthrex SoftStitch
Reference Device	K203117: TissueTak Device
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to expand the indications of the Arthrex SoftStitch to include Rotator Cuff Augmentation.
Device Description	The Arthrex SoftStitch consists of a suture implant and an implant delivery inserter. The implant is a polyester sheath preloaded on a barbed suture manufactured from #1 USP nylon monofilament. The polyester sheath is coated with beeswax.
Comparison Summary of Technological Characteristics and Modifications Proposed	The proposed and predicate device (K190707) have the same basic design, intended use, packaging, shelf life, biocompatibility profile, and sterilization. The proposed Arthrex SoftStitch is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise new or different questions concerning safety or effectiveness.
Indications for Use	The Arthrex SoftStitch is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including the repair of meniscal tears and fixation of prosthetic or biologic material to soft tissues in minimally invasive and open surgical procedures such as rotator cuff repairs.
Performance Data	Tensile testing was performed on the subject device and compared to the reference device to demonstrate that the modifications do not negatively impact mechanical strength. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Conclusion	The Arthrex SoftStitch is substantially equivalent to the predicate device in which the basic design features and intended use are the same. Any differences between the Arthrex proposed device and the predicate device are considered minor and do not raise 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 device.