September 9, 2022

Arthrex Inc.
Lai Saeteurn
Regulatory Affairs Specialist II
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K221354
Trade/Device Name: Arthrex SutureTape
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: June 17, 2022
Received: June 21, 2022

Dear Lai Saeteurn:

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 Deborah Fellhauer
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K221354

Device Name
Arthrex SutureTape

Indications for Use *(Describe)*
The Arthrex SutureTape is intended for use in soft tissue approximation and/or ligation. The suture may be provided individually or be incorporated as a component, into surgeries where constructs including those with allograft or autograft tissues are used for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared	September 9, 2022
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Lai Saeteurn Regulatory Affairs Specialist II 1-239-598-4302 Ext. 71764 Lai.Saeteurn@Arthrex.com
Name of Device	Arthrex SutureTape
Common Name	Suture
Product Code	GAT
Classification Name	21 CFR 878.5000: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class	II
Predicate Device	K171296: Arthrex SutureTape
Reference Devices	K193575: Arthrex SutureTape K122374: Arthrex Suture
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the Arthrex 0.9 mm SutureTape sutures as a line extension to the Arthrex SutureTape.
Device Description	The Arthrex SutureTape is comprised of non-absorbable sutures made of a polyblend of Ultra High Molecular Weight Polyethylene (UHMWPE) and polyester yarns but may also include nylon yarns. The Arthrex 0.9 mm SutureTape is a 0.9 mm-wide tape suture with a round braided suture tail that is smaller than the tape portion. The tape and tail portion of the suture are implantable while the suture tail is not intended to be knotted. The flat tape portion of the Arthrex 0.9 mm SutureTape suture meets or exceeds USP performance standards for knot pull tensile strength for size 2 non-absorbable surgical sutures. The suture tail portions of the Arthrex 0.9 mm SutureTape suture meet the performance standards for USP 2-0 non-absorbable surgical suture, except for an oversize in diameter. The Arthrex 0.9 mm SutureTape is supplied sterile, in pre-cut lengths, in various loop configurations, and in some cases, with various swaged needles and with stiffened ends. The Arthrex 0.9 mm SutureTape is available non-dyed, dyed, and fully or partially striped. Dyes may include D&C Blue No. 6 and Logwood Black. Suture strands that are dyed with Logwood black are made of nylon. Additional material for the Arthrex 0.9 mm SutureTape includes cyanoacrylate.
Indications for Use	The Arthrex SutureTape is intended for use in soft tissue approximation and/or ligation. The suture may be provided individually or be incorporated as a component, into surgeries where constructs including those with allograft or autograft tissues are used for repair.
Performance Data	The flat tape portion of the Arthrex 0.9 mm SutureTape suture meets or exceeds USP performance standards for knot pull tensile strength for size 2 non-absorbable surgical sutures. The suture tail portions of the Arthrex 0.9 mm SutureTape suture meet the performance standards for USP 2-0 non-absorbable surgical suture, except for an oversize in diameter. The attached needle at the suture tail portion of the Arthrex 0.9 mm SutureTape suture meets or exceeds USP performance standards for needle pull tensile strength for size 2-0 non-absorbable surgical sutures.

	Bacterial Endotoxins Test (BET) was performed on the representative samples utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14 to demonstrate that the proposed device meets pyrogen limit specifications.
Technological Comparison	The Arthrex 0.9 mm SutureTape suture is a line extension to the predicate device. In comparison to the predicate device, the Arthrex 0.9 mm SutureTape suture share the same basic design features (e.g., flat braided with round-braided suture tails, non-USP size), fundamental scientific technology, intended use, materials (e.g., yarns, dyes, additive), shelf life, surgical technique, manufacturing, packaging, and sterilization processes as the predicate device. However, the Arthrex 0.9 mm SutureTape suture has a tape width and suture tail diameter range smaller than that of the predicate.
Conclusion	The Arthrex 0.9 mm SutureTape devices are substantially equivalent to the predicate device in which the basic design features, materials, manufacturing, and intended use are the same. Any differences between the proposed and predicate devices are considered minor and do not raise questions concerning safety or effectiveness. Based on the indication or use, technological characteristics, and the tensile test data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate device.