July 24, 2020

Arthrex Inc.
Ivette Galmez
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K193575
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 25, 2020
Received: June 26, 2020

Dear Ivette Galmez:

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,

Cindy Chowdhury, Ph.D., M.B.A.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193575

Device Name

Arthrex SutureTape

Indications for Use *(Describe)*

The Arthrex SutureTape is intended for use in soft tissue approximation and or ligation. These sutures may be incorporated, as components, 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.

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1. 510(k) Summary

Date Prepared	July 21, 2020
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Ivette Galmez Senior Regulatory Affairs Specialist 1-239-643-5553, ext. 71263 ivette.galmez@arthrex.com
Name of Device	Arthrex SutureTape
Common Name	Soft Tissue Fixation Device
Product Code	GAT
Classification Name	21 CFR 878.5000: Non-absorbable poly(ethylene terephthalate) surgical suture
Regulatory Class	Class II
Predicate Device	K171296: SutureTape
Reference Device	K122374: Arthrex Suture K041553: Arthrex Suture Grafting Kit K032245: Arthrex FiberTape Family
Purpose of Submission	This 510(k) premarket notification is submitted to obtain clearance for Arthrex SutureTape suture with new colorant additives per 21 CFR 73.1015 and 21 CFR 74.3054.
Device Description	Arthrex SutureTape is a suture made of Ultra High Molecular Weight Polyethylene (UHMWPE) and polyester, and may include nylon. The proposed suture is braided flat with round ends, and is available in precut lengths in straight and loop configurations, and with or without needles. Arthrex SutureTape is packaged sterile for single use. New colorant additives meet the requirements of 21 CFR 73.1015 and 21 CFR 74.3054.
Indications for Use	Arthrex SutureTape is intended for use in soft tissue approximation and or ligation. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair.
Performance Data	Mechanical testing demonstrated that the strength of the proposed Arthrex SutureTape (straight pull, knot pull and needle pull) met the criteria established by the predicate device. Biocompatibility testing was conducted on the proposed Arthrex SutureTape in accordance with ISO 10993-1:2018. Bacterial Endotoxin test was conducted 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.
Conclusion	The Arthrex SutureTape is substantially equivalent to the predicate device in which the basic design features, materials, manufacturing and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise questions concerning safety or 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.