DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2017

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

Re: K171296
Trade/Device Name: SutureTape
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: April 28, 2017
Received: May 2, 2017

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.5 INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171296

Device Name

SutureTape

Indications for Use *(Describe)*

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 tissue 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

Date Summary Prepared	May 25, 2017
Manufacturer/Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Ivette Galmez Senior Regulatory Affairs Specialist Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: (239) 643-5553, ext. 71263 Fax: (239) 598-5508 Email: igalmez@arthrex.com
Trade Name	***SutureTape***
Common Name	Soft Tissue Fixation Device
Product Code - Classification Name	GAT Nonabsorbable poly(ethylene terephthalate) surgical suture
CFR	21 CFR 878.5000
Predicate Device	K122374: Arthrex Suture
Reference Predicates	K041553: Arthrex Suture Grafting Kit K032245: Arthrex FiberTape Family K151230: Arthrex FiberTak
Purpose of Submission	This special 510(k) premarket notification is submitted to obtain clearance for **SutureTape**. The proposed SutureTape was cleared as a component of Arthrex FiberTak (K151230).
Device Description	*SutureTape* is a braided 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 has a width of 1.3 mm. SutureTape is available in precut lengths in straight and loop configurations, and with or without needles. SutureTape is packaged sterile for single use. SutureTape meets USP standards for size 2 suture, except for an oversize in diameter. The *SutureTape* modifications as compared to the predicate device(s) include smaller tape width (1.3mm vs. 1.5mm), lack of a suture core and different braiding pattern of colored yarns. Additionally, SutureTape is braided flat similar to the cleared LabralTape (K122374) but has round suture tails similar to the cleared FiberTape (K032245).

Intended Use	*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	The submitted mechanical testing demonstrates that the strength of the proposed *SutureTape* (straight pull, knot pull and needle pull) exceeds that of the USP requirements for size 2 suture. This specification is based on the diameter of the suture ends, which span USP size 1 and 2 diameter ranges. Bacterial endotoxin testing per EP 2.6.14/USP <85> was conducted to demonstrate that the subject device meets pyrogen limit specifications. *SutureTape* is similar to the predicate devices in which the basic design features and intended use 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. The suture materials and the manufacturing, packaging, and sterilization processes are the same as those used for the predicate and reference devices. The biocompatibility and shelf life for the proposed *SutureTape* were reviewed and determined to be acceptable due to its similarities with the predicate. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that *SutureTape* is substantially equivalent to currently marketed predicate device.