October 2, 2020

Arthrex Inc.
David Rogers
Regional Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K190707
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: August 24, 2020
Received: September 1, 2020

Dear Mr. Rogers:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190707

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.

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	October 2, 2020
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	David L Rogers Regional Manager, Regulatory Affairs 1-239-643-5553, ext. 71924 david.rogers@arthrex.com
Name of Device	Arthrex SoftStitch
Common Name	Fastener, fixation, nondegradable soft tissue
Product Code	GAT – Nonabsorbable polyethylene surgical suture
Classification Name	21 CFR 878.5000 – Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class	II
Predicate Device	K132043: Arthrex SpeedCinch K073149: Arthrex Meniscal Cinch
Reference Device	K052900: Quill Nonabsorbable Nylon Barbed Suture K181769: Arthrex FiberTak Suture Anchor K162396: SILK Surgical Suture
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex SoftStitch as a line extension to the Arthrex All Inside Meniscal Repair devices cleared under K132043 and K073149.
Device Description	The Arthrex SoftStitch is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including the repair of meniscal tears. The Arthrex SoftStitch consists of a suture implant and an implant delivery inserter. The implant is a polyester sheath preloaded on a wax coated barbed suture manufactured from nylon monofilament.
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.
Technological Comparison	The Arthrex SoftStitch is substantially equivalent to the predicate devices cleared under K132043 and K073149 in which the basic design features, intended use, fundamental scientific technology, sterility, packaging and shelf-life are identical. Compared to the predicate, the SoftStitch delivers a polyester soft anchor with a barbed suture as opposed to a hard anchor (PEEK) delivery with a braided suture design. The soft anchor is delivered through a push rod mechanism instead of a trigger design.
Performance Data	Cyclic pull-out testing and arthroscopic/histologic imaging from a canine functional meniscus implant study were performed to demonstrate that the Arthrex SoftStitch performs substantially equivalent to the predicate devices. Cytotoxicity, Sensitization, Irritation, Genotoxicity, Systemic Toxicity, Subchronic/Subacute Toxicity, Implantation and Material Characterization testing was conducted on the Arthrex SoftStitch in accordance with ISO 10993-1:2018. Assessment of physical product attributes including product design, size, and materials as well as the conditions of manufacture and packaging has determined that the Arthrex SoftStitch does not introduce additional risks or concerns regarding

	sterilization and shelf-life. 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 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 device.