October 25, 2021

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

Re: K212146
Trade/Device Name: Arthrex LoopLoc™ Knotless Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: July 27, 2021
Received: July 28, 2021

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,

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.

Submission Number *(if known)*

K212146

Device Name

Arthrex LoopLoc™ Knotless Suture

Indications for Use *(Describe)*

The Arthrex LoopLoc™ Knotless Suture is intended for soft-tissue approximation for hip capsular closure.

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 19, 2021
Contact Details	Arthrex, Inc. 1370 Creekside Boulevard Naples FL 34108 US 239-598-4302 Ms. Lai Saeteurn Lai.Saeteurn@Arthrex.com
Device Trade Name	Arthrex LoopLoc™ Knotless Suture
Common Name	Nonabsorbable poly (ethylene terephthalate) surgical suture
Classification Name	Suture, Nonabsorbable, Synthetic, Polyethylene
Regulation Number	878.5000
Product Code	GAT
Predicate Device	K122374: Arthrex Suture K041553: Arthrex Suture Grafting Kit
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex LoopLoc™ Knotless Suture.
Device Description	The Arthrex LoopLoc™ Knotless Suture is an all-suture device intended for use in soft-tissue approximation for hip capsular closure. This device is composed of a nonabsorbable suture implant and shuttling suture that are braided polyblend sutures (Arthrex size #2) made of ultra-high molecular weight polyethylene (UHMWPE) and polyester (PET) sutures, and preloaded on a single-use high-density polyethylene (HDPE) card with a disposable suture threader made of low-density polyethylene (LDPE), stainless steel, and Nitinol wire.
Indications for Use	The Arthrex LoopLoc™ Knotless Suture is intended for soft-tissue approximation for hip capsular closure.
Indications for Use Comparison	The Arthrex LoopLoc™ Knotless Suture is indicated for hip capsular closure whereas the predicate devices are indicated for soft tissue approximation and/or ligation. However, the intended use, soft tissue approximation, remains unchanged.
Technological Comparison	The Arthrex LoopLoc™ Knotless Suture has the same intended use, materials, biocompatibility profile, packaging configuration, shelf-life, and sterilization method as the cleared predicate devices. Any technological differences between the proposed and predicate devices are considered minor and can be mitigated by cyclic and ultimate load testing performed using clinically relevant parameters. Therefore, the proposed device is substantially equivalent to the predicate devices.
Non-Clinical and/or Clinical Tests Summary & Conclusions	Cyclic and ultimate load testing was conducted on the Arthrex LoopLoc™ Knotless Suture and submitted in this Traditional 510(k). Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications. The test data demonstrates that the proposed device can maintain knotless integrity and withstand cyclic loads greater than anticipated during the rehabilitation period following arthroscopic hip surgery. The specific hip capsular closure indication does not increase risk greater than the previously cleared general soft tissue approximation with respect to improper selection and use, suture breakage, and adverse tissue reaction. Therefore, the proposed device is substantially equivalent to the cleared Arthrex suture devices for soft tissue approximation. Based on the intended use, technological characteristics, and the bench testing submitted, Arthrex, Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate devices.