August 22, 2022

Arthrex Inc.
Kelsey Roberts
Sr. Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K221485
Trade/Device Name: Arthrex FiberTape and TigerTape Cerclage Sutures
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN, HWC, JDQ, GAT
Dated: May 20, 2022
Received: May 24, 2022

Dear Kelsey Roberts:

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.

510(k) Number *(if known)*
K221485

Device Name

Arthrex FiberTape and TigerTape cerclage sutures

Indications for Use *(Describe)*

Arthrex FiberTape and TigerTape cerclage sutures are 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.

When used as bone fixation cerclage the sutures are intended for:
• Trochanteric reattachment after trochanteric osteotomy following total hip arthroplasty
• Sternotomy indications including the "rewiring" of osteomized sternums
• Trauma surgery indications including olecranon, ankle, patella and some shoulder fracture rewiring
- Treatment of anterior glenoid bone loss using the Latarjet or bone block procedure (allograft or autograft)
•Repair of long bone fractures due to trauma or reconstruction

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	August 22, 2022
510(k) Number	K221485
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Kelsey N. Roberts Sr. Regulatory Affairs Specialist 1-239-643-5553, ext. 72257 Kelsey.Roberts@arthrex.com
Name of Device	Arthrex FiberTape and TigerTape Cerclage Sutures
Common Name	Bone Fixation Cerclage, Suture
Product Code	HTN HWC JDQ GAT
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener 21 CFR 888.3010: Bone Fixation Cerclage 21 CFR 878.5000: Nonabsorbable Poly(ethylene) Terephthalate Surgical Suture
Regulatory Class	II
Predicate Device	K183232 Double ENDOBUTTON Fixation Device
Reference Device	K170206 Arthrex FiberTape Cerclage K122374 Arthrex Suture
Purpose of Submission	This traditional 510(k) premarket notification is submitted to obtain the indication of anterior glenoid bone loss using the Laterjet or bone block procedure (allograft or autograft) for the Arthrex FiberTape and TigerTape Cerclage Sutures.
Device Description	The proposed Arthrex FiberTape and TigerTape Cerclage devices are available as a flat braided suture assembled in a loop configuration. Cerclage is assembled on an HDPE card or on an ABS loader. The devices are manufactured from a polyblend of Ultra High Molecular Weight Polyethylene (UHMWPE) and polyester materials. These materials are identical to those cleared in K170206. For the loop assembly, the looped end of the suture is tied as a hitch over a sheath that secures a double loop.
Comparison Summary of Technological Characteristics and Modifications Proposed	The proposed devices have the same technological characteristics (device design, sterilization, and biocompatibility). The proposed device modification consists of the additional indication of anterior glenoid bone loss using the Laterjet or bone block procedure. The Arthrex FiberTape and TigerTape cerclage sutures are substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise new or different questions concerning safety or effectiveness.
Indications for Use	Arthrex FiberTape and TigerTape cerclage sutures are 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. When used as bone fixation cerclage the sutures are intended for: • Trochanteric reattachment after trochanteric osteotomy following total hip arthroplasty

	• Sternotomy indications including the "rewiring" of osteomized sternums • Trauma surgery indications including olecranon, ankle, patella and some shoulder fracture rewiring - Treatment of anterior glenoid bone loss using the Latarjet or bone block procedure (allograft or autograft) •Repair of long bone fractures due to trauma or reconstruction
Performance Data	Tensile and pressure distribution testing was performed on the subject device and compared to the predicate device to demonstrate that the modifications do not negatively impact mechanical strength. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Clinical Literature	Clinical literature was provided to justify the testing conditions and acceptance criteria of the subject Arthrex Cerclage Sutures.
Conclusion	The Arthrex FiberTape and TigerTape Cerclage Sutures are 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.