October 6, 2023

Arthrex Inc.
Ruth Segall
Regulatory Affairs Specialist I
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K232755
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: September 7, 2023
Received: September 8, 2023

Dear Ruth Segall:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and

21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher Ferreira -S

for

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*

K232755

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
• To provide fixation during the healing process following syndesmotic trauma, such as fixation of acromioclavicular separation due to coracoclavicular ligament disruption.

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 6, 2023
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Ruth Segall Regulatory Affairs Specialist I 1-239-598-4302, ext. 71764 Ruth.Segall@arthrex.com
Trade Name	Arthrex FiberTape and TigerTape Cerclage Sutures
Common Name	Bone Fixation Cerclage, Suture and Washer
Product Code	HTN – Primary Product Code 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
Primary Predicate Device	K220947 Arthrex Knotless AC Repair Devices
Reference Devices	K221485 Arthrex FiberTape and TigerTape Cerclage Sutures K170206 Arthrex FiberTape Cerclage
Purpose of Submission	This special 510(k) premarket notification is submitted to obtain the additional indication to provide fixation during the healing process following syndesmotic trauma, such as fixation of acromioclavicular separation due to coracoclavicular ligament disruption for the Arthrex FiberTape and TigerTape Cerclage Sutures.
Device Description	The proposed Arthrex FiberTape and TigerTape Cerclage Sutures are available as flat braided sutures assembled in a loop configuration. The devices are manufactured from a polyblend of Ultra High Molecular

	Weight Polyethylene (UHMWPE), polyester, and nylon materials. These materials are identical to those cleared in K221485 and K170206. For the loop assembly, the looped end of the suture is tied as a hitch over a sheath that secures a double loop or tied over the post of an ABS loader. The proposed Arthrex FiberTape and TigerTape Cerclage Sutures may be used with or without the cleared Arthrex Dog Bone Button (K220947).
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 • To provide fixation during the healing process following syndesmotic trauma, such as fixation of acromioclavicular separation due to coracoclavicular ligament disruption.
Performance Data	The submitted testing data, ultimate load and cyclic displacement, demonstrates that the Arthrex FiberTape and TigerTape Cerclage Sutures are substantially equivalent to the predicate device Arthrex Knotless AC

	Repair Devices (K220947). Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Technological Comparison	Compared to the predicate device Arthrex Knotless AC Repair Devices (K220947) and reference devices Arthrex FiberTape and TigerTape Cerclage Sutures (K221485) and Arthrex FiberTape Cerclage (K170206), the proposed Arthrex FiberTape and TigerTape Cerclage Sutures have identical materials, fundamental scientific technology, packaging, sterility, shelf-life, and MRI safety labeling. The proposed device is an all-suture cerclage construct that may be used with up to one button for the surgical technique; whereas the predicate device is a suture construct used with two metal buttons (either pre-assembled or attached). Based on the intended use, fundamental scientific technology, and the data provided in this Special 510(k), Arthrex has determined that the proposed Arthrex FiberTape and TigerTape Cerclage Sutures are substantially equivalent to the predicate device Arthrex Knotless AC Repair Devices, K220947 and reference devices, Arthrex FiberTape and TigerTape Cerclage Sutures, K221485 and Arthrex FiberTape Cerclage, K170206. Any differences between the proposed device and predicate device are considered minor and do not raise different questions concerning safety and effectiveness.
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 identical. 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.