February 20, 2025

Arthrex Inc.
Emmarie Halteman
Sr. Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108

Re: K243344
Trade/Device Name: Arthrex FiberTape and TigerTape Cerclage Sutures; Arthrex Radiopaque FiberTape Cerclage Sutures
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ, GAT
Dated: January 17, 2025
Received: January 21, 2025

Dear Emmarie Halteman:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Christopher Ferreira, M.S.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243344

Device Name

Arthrex FiberTape and TigerTape Cerclage Sutures;
Arthrex Radiopaque FiberTape Cerclage Sutures

Indications for Use *(Describe)*

Arthrex FiberTape and Tiger Tape Cerclage sutures and Arthrex Radiopaque FiberTape 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
• Provide fixation during the healing process following syndesmotic trauma, such as fixation of acromioclavicular separation due to coracoclavicular ligament
• Spinal applications including sublaminar and intrafacet wiring of the spinal column

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.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary

Date Prepared	February 20, 2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Emmarie Halteman Title: Senior Regulatory Affairs Specialist Phone: 1-239-643-5553 Email: emmarie.halteman@arthrex.com
Trade Name	Arthrex FiberTape and TigerTape Cerclage sutures Arthrex Radiopaque FiberTape Cerclage sutures
Common Name	Bone Fixation Cerclage
Product Code	Primary: JDQ Additional: GAT
Classification Name	**21 CFR 888.3010: Bone Fixation Cerclage** 21 CFR 878.5000: Nonabsorbable Poly(ethylene) Terephthalate
Regulatory Class	II
Primary Predicate Device	K181749: Kinamed SuperCable® Iso-Elastic™ Cerclage System
Additional Predicate Devices	K232755: Arthrex FiberTape and TigerTape Cerclage sutures
Reference Devices	K230976: Arthrex Radiopaque FiberTape Cerclage sutures
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to expand and align the indications for Arthrex Radiopaque FiberTape Cerclage Sutures and Arthrex FiberTape & TigerTape Cerclage Sutures.
Device Description	The **Arthrex Radiopaque FiberTape Cerclage sutures** are non-absorbable braided sutures composed of Ultra High Molecular Weight Polyethylene (UHMWPE) which incorporates Bismuth Trioxide (Bi2O3), and Polyester yarns over a core of suture also made with Ultra High Molecular Weight Polyethylene (UHMWPE) with Bismuth Trioxide (Bi2O3), and Polyester. Dyes include D&C Blue No. 6. The UHMWPE is naturally yellow due to the addition of Bismuth Trioxide (Bi2O3). The sutures are assembled on an ABS loader. The sutures may also contain a FiberLink shuttling suture that is used for passing only. The **Arthrex FiberTape and TigerTape Cerclage Sutures** are non-absorbable braided sutures composed of Ultra High Molecular Weight Polyethylene, polyester, and possibly nylon yarns over a core of FiberWire or TigerWire Suture (each made of UHMWPE and polyester). FiberTape differs from TigerTape in color and materials. FiberTape is blue/white suture consisting of UHMWPE and polyester. TigerTape suture is white/black consisting of UHMWPE, polyester, and nylon. Additional materials include cyanoacrylate at the suture ends which are cut off during the procedure. Dyes include D&C Blue No. 6 and Logwood Black. 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.
Indications for Use	Arthrex FiberTape and Tiger Tape Cerclage sutures and Radiopaque FiberTape 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 • Provide fixation during the healing process following syndesmotic trauma, such as fixation of acromioclavicular separation due to coracoclavicular ligament • Spinal applications including sublaminar and intrafacet wiring of the spinal column
Performance Data	The submitted testing data, dynamic tensile fatigue testing in fluid for 5 million cycles, demonstrates that the Arthrex Radiopaque FiberTape Cerclage and Arthrex FiberTape & TigerTape Cerclage sutures are substantially equivalent to the primary predicate Kinamed SuperCable Iso-Elastic Cerclage System (K181749) and secondary predicate Arthrex FiberTape and TigerTape Cerclage sutures (K232755). These predicate equivalences support the inclusion of the proposed indications for the subject Arthrex Radiopaque FiberTape Cerclage and Arthrex FiberTape & TigerTape Cerclage sutures. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the devices meet pyrogen limit specifications.
Technological Comparison	Compared to the secondary predicate Arthrex FiberTape and TigerTape Cerclage sutures (K232755), and reference device Arthrex Radiopaque FiberTape Cerclage sutures (K230976), the subject Arthrex Radiopaque FiberTape Cerclage and Arthrex FiberTape & TigerTape Cerclage sutures have the same intended use, materials, fundamental scientific technology, design, packaging, sterility, shelf-life, and MRI safety labeling.

	The subject devices will include the addition of spinal applications cleared via K181749, and acromioclavicular (AC) indication cleared via K232755 to the indications for use. Based on the intended use, fundamental scientific technology, and the data provided in this Traditional 510(k), Arthrex has determined that the subject Arthrex Radiopaque FiberTape Cerclage and Arthrex FiberTape & TigerTape Cerclage sutures are substantially equivalent to the predicate devices cleared under Kinamed SuperCable Iso-Elastic Cerclage System (K181749) and Arthrex FiberTape and TigerTape Cerclages Sutures (K232755). Any differences between the subject and predicate devices are considered minor and do not raise new or different questions concerning safety and effectiveness.
Conclusion	The Arthrex Radiopaque FiberTape Cerclage and Arthrex FiberTape & TigerTape Cerclage sutures are substantially equivalent to the predicate devices in which the intended use and basic design features are the same. Any differences between the subject devices and the predicate devices are considered minor and do not raise questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the subject devices are substantially equivalent to the currently marketed predicate devices.