August 24, 2023

Arthrex, Inc
Stacy Valdez
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K230976
Trade/Device Name: 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: July 24, 2023
Received: July 25, 2023

Dear Stacy Valdez:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal 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)*
K230976

Device Name
Arthrex Radiopaque FiberTape cerclage sutures

Indications for Use *(Describe)*
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

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	07/24/2023
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Stacy Valdez Senior Regulatory Affairs Specialist 1-239-643-5553, ext. 72010 Stacy.valdez@arthrex.com
Name of Device	Arthrex Radiopaque FiberTape Cerclage sutures
Common Name	Bone Fixation Cerclage
Product Code	JDQ (Primary), GAT
Classification Name	21 CFR 888.3010: Bone Fixation Cerclage (Primary) 21 CFR 878.5000: Nonabsorbable Poly(ethylene) Terephthalate
Regulatory Class	II
Predicate Device	K221485: Arthrex FiberTape and TigerTape Cerclage Sutures
Additional Predicate Device	K143716: DSM Biomedical DRP Cable
Reference Device(s)	K170206: Arthrex FiberTape Cerclage K193575: Arthrex SutureTape
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Radiopaque FiberTape Cerclage Sutures.
Device Description	The Arthrex Radiopaque FiberTape Cerclage sutures are non-absorbable braided sutures assembled on an ABS loader. The Radiopaque FiberTape Cerclage implant is hitched around the post of the ABS loader which allows the nitinol wire to pass through the knot. The devices are manufactured from a polyblend of Ultra High Molecular Weight Polyethylene (UHMWPE) which incorporates Bismuth Trioxide (Bi_2O_3), and polyester materials.
Indications for Use	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
Performance Data	The submitted testing data, tensile strength, cyclic displacement, and creep displacement, demonstrates that the Arthrex Radiopaque FiberTape Cerclage sutures are substantially equivalent to the additional predicate device DSM Biomedical DRP Cable (K143716). Bacterial Endotoxins Test (BET) was performed on the Arthrex Radiopaque FiberTape Cerclage Sutures per EP 2.6.14/USP <85> to

	demonstrate that the device meets pyrogen limit specifications.
Technological Comparison	Compared to the primary predicate device Arthrex FiberTape and TigerTape Cerclage Sutures (K221485) and additional predicate device DSM Biomedical DPR Cable (K143716), the proposed Arthrex Radiopaque FiberTape Cerclage sutures have the same fundamental scientific technology, design, packaging, sterility, shelf-life, and MRI safety labeling. The proposed Arthrex Radiopaque FiberTape Cerclage sutures contain UHMWPE which incorporates Bismuth Trioxide (Bi_2O_3); whereas the primary predicate device Arthrex FiberTape and TigerTape Cerclage sutures (K221485) do not contain Bismuth Trioxide (Bi_2O_3). However, the Cerclage sutures cleared under additional predicate device DSM Biomedical DPR Cable (K143716) contain UHMWPE which incorporates Bismuth Trioxide (Bi_2O_3). Any differences between the proposed devices and the predicate devices are considered minor and do not raise new or different questions concerning safety or effectiveness.
Conclusion	The Arthrex Radiopaque FiberTape 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 proposed device and the predicate device are considered minor and do not raise 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.