November 15, 2017

Arthrex, Inc.
Ms. Ivette Galmez
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K170206
Trade/Device Name: Arthrex FiberTape Cerclage
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ, GAT
Dated: October 18, 2017
Received: October 19, 2017

Dear Ms. Galmez:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170206

Device Name

Arthrex FiberTape Cerclage

Indications for Use *(Describe)*

The Arthrex FiberTape Cerclage suture is 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 a bone fixation cerclage the suture is intended for:

- Trochanteric reattachment after trochanteric osteotomy following total hip arthroplasty.
- Sternotomy indications including the "rewiring" of osteotomized sternums.
- Trauma surgery indications including olecranon, ankle, patella and some shoulder fracture rewiring.
- 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

1. 510(k) Summary

Date Prepared	November 13, 2017
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Ivette Galmez Senior Regulatory Affairs Specialist 1-239-643-5553, ext. 71263 Ivette.galmez@arthrex.com
Name of Device	Arthrex FiberTape Cerclage
Common Name	Bone Fixation Cerclage, Suture
Product Code	JDQ, GAT
Classification Name	21 CFR 888.3010: Bone Fixation Cerclage 21 CFR 878.5000: Nonabsorbable Poly(ethylene) Terephthalate Surgical Suture
Regulatory Class	II
Predicate Device	K143716: DSM Biomedical DPR Cable
Reference Predicate	K102834: ISO-Elastic Cerclage System K032245: Arthrex FiberTape Family K041553: Arthrex Suture Grafting Kit K122374: Arthrex Suture
Purpose of Submission	This traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex FiberTape Cerclage sutures for use as bone fixation cerclage. This Arthrex FiberTape Cerclage submission is comprised of four suture devices, two of which (FiberTape® and TigerTape™) have been previously cleared in K032245, K041553 and K122374.
Device Description	The Arthrex FiberTape Cerclage suture is available as a flat braided suture or assembled in a loop configuration. The Arthrex FiberTape Cerclage suture is braided from a polyblend of Ultra High Molecular Weight Polyethylene (UHMWPE) and polyester materials identical to those used in other cleared Arthrex sutures (K032245, K041553 and K122374). For the loop assembly, the looped end of the suture is tied as a hitch over a sheath that secures a double looped suture.
Intended Use	The Arthrex FiberTape Cerclage suture is 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 suture is 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 • Repair of long bone fractures due to trauma or reconstruction

Substantial Equivalence Summary	The Arthrex FiberTape Cerclage suture is substantially equivalent to the predicate devices, in which the basic design features and intended uses are the same. Any differences between the Arthrex FiberTape Cerclage and the predicates are considered minor and do not raise new questions concerning safety and effectiveness. The submitted testing data, fatigue strength, tensile force, creep and knot strength demonstrates that the Arthrex FiberTape Cerclage is substantially equivalent to the cleared DSM Biomedical DPR Cable and the Kinamed ISO-Elastic Cerclage System. Wear testing with particle analysis and comparative testing demonstrated no statistical significant differences between the proposed Arthrex FiberTape Cerclage and the cleared DSM Biomedical DPR Cable. Bacterial Endotoxins Test was performed in accordance to USP <85> to demonstrate that the device meets pyrogen limit specifications. Based on the indication for use, the technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the Arthrex FiberTape Cerclage suture is substantially equivalent to currently marketed predicate devices.