10/27/2022

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

Re: K220880
Trade/Device Name: Arthrex BioSuture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: September 2, 2022
Received: September 7, 2022

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,

Deborah Fellhauer RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*

K220880

Device Name
Arthrex BioSuture

Indications for Use *(Describe)*

The Arthrex BioSuture is intended for 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.

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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"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	October 17, 2022
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 BioSuture
Common Name	Suture
Product Code	GAT
Classification Name	21 CFR 878.5000: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class	II
Primary Predicate Device	K112899: Arthrex Bio-Suture
Additional Predicate Device	K140019: Arthrex BioSuture
Reference Devices	K193575: Arthrex SutureTape K122374: Arthrex Suture K041553: Arthrex Suture Grafting Kit K032245: Arthrex FiberTape Family K021434: Arthrex FiberWire Family, USP Size Sutures
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the Arthrex BioSuture.
Device Description	The proposed Arthrex BioSuture is a braided construct made of Ultra High Molecular Weight Polyethylene (UHMWPE) and polyester and coated with collagen coating. The proposed suture is braided flat with round ends and may be available in precut lengths in straight and loop configurations. The Arthrex BioSuture is packaged sterile for single use. The Arthrex BioSuture is a line extension to the Arthrex Bio-Suture consisting of a new size.
Indications for Use	The Arthrex BioSuture is intended for 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.
Performance Data	Mechanical testing (straight pull, knot pull) was conducted to demonstrate that the strength of the proposed Arthrex BioSuture met the established acceptance criteria. Bacterial Endotoxins Test (BET) was performed on the representative samples utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14 to demonstrate that the proposed device meets pyrogen limit specifications.
Technological Comparison	The Arthrex BioSuture is substantially equivalent to the predicate devices cleared under K112899 and K140019 in which the overall design and configuration of the suture, intended use/indications, surgical technique, fundamental scientific technology, sterility, materials, packaging and manufacturing process are identical. The Arthrex BioSuture has a smaller tape width and round suture

	diameter than the predicate devices cleared under K112899. The Arthrex BioSuture is labeled with a 4-year shelf life; whereas the predicate devices cleared under K112899 are labeled with a 2-year shelf life. However, the additional predicate devices cleared under K140019 are labeled with a 4-year shelf life. The Arthrex BioSuture has been evaluated for MR Safe labeling; whereas the predicate devices cleared under K112899 were not evaluated for MR Safe labeling. The needles are not implantable and therefore have not been evaluated for MR Safety. The Arthrex BioSuture is a line extension to the predicate devices, which include minor dimensional modifications with no change to intended use or function. Any differences between the Arthrex BioSuture and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex BioSuture is substantially equivalent to the predicate device in which the overall design and configuration of the suture, the intended use/indications, surgical technique, fundamental scientific technology, sterility, materials, packaging, and manufacturing process remain identical to the primary predicate Arthrex Bio-Suture (K112899) and additional predicate Arthrex BioSuture (K140019). Any differences between the proposed device and the predicate device are considered minor and do not raise different questions concerning safety or effectiveness. Mechanical testing (straight pull, knot pull) demonstrated that the strength of the proposed Arthrex BioSuture is substantially equivalent to that of the predicate device for the desired indications. 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.