October 27, 2026

Arthrex, Inc.
Landon Smith
Regulatory Affairs Specialist, II
1370 Creekside Blvd.
Naples, Florida 34108

Re: K263477
Trade/Device Name: Arthrex FiberButton
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 28, 2026
Received: September 29, 2026

Dear Landon Smith:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

THOMAS MCNAMARA -S

For: 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K263477

Please provide the device trade name(s).

Arthrex FiberButton

Please provide your Indications for Use below.

The Arthrex FiberButton (10 mm x 6 mm, 14 mm x 8 mm) is intended for use with Arthrex suture anchors and/or Arthrex suture for orthopedic use.

The Arthrex FiberButton (18 mm x 10 mm) is intended for use with Arthrex Suture Anchors and/or Arthrex Suture for orthopedic use and the treatment of anterior glenoid bone loss using the Latarjet or bone block procedure (allograft or autograft).

The Arthrex FiberButton is not intended for stand-alone use, and is intended to be used in accordance with the cleared Indications for Use for the Arthrex Suture Anchors (8 mm and smaller) and Arthrex Sutures (FiberWire®: sizes #4-0, #3-0, #2-0, #1-0, #0, #1, #2, #3, #4, and #5; FiberTape®: sizes 2.2 and 1.7 mm; SutureTape: sizes 0.9, 1.7 and 1.3 mm; materials: UHMWPE, polyester and nylon) for orthopedic use.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

Date Prepared	September 25, 2026
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Landon Smith Regulatory Affairs Specialist, II 239-643-5553 ext. 77024
Trade Name	Arthrex FiberButton
Common Name	Fastener, fixation, nondegradable, soft tissue
Product Code	MBI
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Primary Predicate Device	K260018 – Arthrex FiberButton
Additional Predicate Devices	K232755 - Arthrex FiberTape and TigerTape Cerclage Sutures K221485 - Arthrex FiberTape and TigerTape Cerclage Sutures
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance of the Arthrex FiberButton
Device Description	The Arthrex FiberButton is an implantable nonabsorbable device intended to be used with Arthrex Suture for soft tissue approximation and/or ligation and/or with Arthrex Suture Anchors for suture (soft tissue) to bone fixation. The FiberButton is an oval button made of polyester yarns embroidered over a woven fabric. Suture colorants include D&C Blue No. 6. The Arthrex FiberButton is available in one size (18 mm x 10 mm), provided sterile (Ethylene Oxide) for single-use and is packaged in a dual barrier configuration. The Arthrex Suture Anchors and Arthrex Suture are sold separately.
Indications for Use	The Arthrex FiberButton (10 mm x 6 mm, 14 mm x 8 mm) is intended for use with Arthrex suture anchors and/or Arthrex suture for orthopedic use.

	The Arthrex FiberButton (18 mm x 10 mm) is intended for use with Arthrex Suture Anchors and/or Arthrex Suture for orthopedic use and the treatment of anterior glenoid bone loss using the Latarjet or bone block procedure (allograft or autograft). The Arthrex FiberButton is not intended for stand-alone use, and is intended to be used in accordance with the cleared Indications for Use for the Arthrex Suture Anchors (8 mm and smaller) and Arthrex Sutures (FiberWire®: sizes #4-0, #3-0, #2-0, #1-0, #0, #1, #2, #3, #4, and #5; FiberTape®: sizes 2.2 and 1.7 mm; SutureTape: sizes 0.9, 1.7 and 1.3 mm; materials: UHMWPE, polyester and nylon) for orthopedic use.
Performance Data	To address the risk of tissue pull through, Arthrex conducted testing to ensure the pull through strength of #2 FiberTape and #4-0 suture (Arthrex Suture, K122374) with the support of the Arthrex FiberButton shall be greater than the pull through strength of the #2 FiberTape and #4-0 sutures alone. To address the risk of decreased mechanical strength, Arthrex conducted cyclic load testing to ensure the mean strength of the cerclage construct with support of the proposed Arthrex FiberButton shall be statistically non-inferior to the mean strength of the cerclage construct without the FiberButton minus 5% of the mean strength of the historical cerclage construct without the FiberButton (Arthrex FiberTape and TigerTape Cerclage Sutures, K221485).
Technological Comparison	The materials used in the manufacturing and the packaging configuration of the proposed Arthrex FiberButton are identical to those used in the legally marketed Arthrex FiberButton (K260018). The proposed Arthrex FiberButton shares the following characteristics with the primary predicate device and additional predicate devices:

	• Shelf Life – 5 Years • Sterility – Ethylene Oxide • MRI Safety Designation – MRI Safe
Conclusion	The Arthrex FiberButton is substantially equivalent to the primary and additional predicate device in which the basic design features and intended use are the same. Any differences between the proposed device and the primary and additional predicate device are considered minor and do not raise any new or different questions concerning safety and effectiveness. Based on the indications for use, technological characteristics, and the data submitted, Arthrex, Inc. has determined that the proposed device is substantially equivalent to the currently marketed primary and additional predicate devices.