March 9, 2026

Arthrex, Inc.
Alex Underberg
Regulatory Affairs Specialist, Sr.
1370 Creekside Blvd.
Naples, Florida 34108

Re: K260405
Trade/Device Name: FiberTape Button
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, GAT
Dated: February 9, 2026
Received: February 9, 2026

Dear Alex Underberg:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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 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,

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.	K260405

Please provide the device trade name(s).

FiberTape Button

Please provide your Indications for Use below.

The FiberTape Button is intended to be used for fixation of bone to bone or soft tissue to bone and is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering the FiberTape Button for primary or secondary fixation for ACL, PCL, MCL, POL, LCL, MPFL, ALL, PLC, Quadriceps Tendon, and Patellar Tendon repair and reconstruction and Iliotibial Band tenodesis.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Date Prepared	02/09/2026
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Alex Underberg Title: Regulatory Affairs Specialist, Senior Phone: 901-606-4046 Email: Alex.Underberg@Arthrex.com
Trade Name	FiberTape button
Common Name	Fastener, Fixation, Nondegradable, Soft-Tissue
Product Code	MBI, GAT
Classification Name	21 CFR 888.3040: Fastener, Fixation, Nondegradable, Soft-Tissue 21 CFR 878.5000: Suture, Nonabsorbable, Synthetic, Polyethylene
Regulatory Class	Class II
Primary Predicate Device	K241235: Arthrex TightRope II
Additional Predicate Devices	K122374: Arthrex Suture (UHMWPE)
	K203495: Arthrex SwiveLock Anchors
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the FiberTape Button.
Device Description	The FiberTape Button is a suture-button construct comprised of a titanium button and nonabsorbable suture. The device is provided sterile and is single-use.
Indications for Use	The FiberTape Button is intended to be used for fixation of bone to bone or soft tissue to bone and is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering the FiberTape Button for primary or secondary fixation for ACL, PCL, MCL, POL, LCL, MPFL, ALL, PLC, Quadriceps Tendon, and Patellar Tendon repair and reconstruction and Iliotibial Band tenodesis.
Performance Data	Utilizing test methods that align with previously cleared RetroButton within K062747, S.E. 09/29/2006, Arthrex completed straight pull testing and demonstrated that the subject device passed all acceptance criteria for ultimate load and cyclic displacement. In addition, Arthrex has provided evidence of verification, validation, or engineering

	justifications for MRI, Biocompatibility, Packaging, Shelf-Life, Material Stability, and Sterilization.
Technological Comparison	The subject FiberTape Button is similar in design to predicate devices Arthrex TightRope II and Arthrex Suture. The subject device has identical components when compared to the predicate devices except that they are assembled in a new configuration. Any differences between the subject and predicate devices are considered minor and do not raise any new or different questions concerning safety or effectiveness.
Conclusion	The subject FiberTape Button is substantially equivalent to the predicate devices. Any differences between the subject device and the predicate devices are considered minor and do not result in new or different questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex has determined that the subject device is substantially equivalent to the currently marketed predicate devices.