



June 26, 2026

Arthrex, Inc.
Rebecca Homan
Manager, Regulatory Affairs
1370 Creekside Blvd.
Naples, Florida 34108

Re: K260018

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: May 25, 2026
Received: May 26, 2026

Dear Rebecca Homan:

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 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 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.

K260018

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Please provide the device trade name(s).

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Arthrex FiberButton

Please provide your Indications for Use below.

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The Arthrex FiberButton is intended for use with Arthrex Suture Anchors and/or Arthrex Suture for orthopedic use.

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 (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary

<i>Date Prepared</i>	June 15, 2026
<i>Submitter</i>	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
<i>Contact Person</i>	Rebecca R. Homan Manager, Regulatory Affairs 239-598-4302 ex. 73429 Rebecca.Homan@Arthrex.com
<i>Trade Name</i>	Arthrex FiberButton
<i>Common Name</i>	Fastener, fixation, nondegradable, soft tissue
<i>Product Code</i>	MBI
<i>Classification Name</i>	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
<i>Regulatory Class</i>	II
<i>Primary Predicate Device</i>	K193157 – Arthrex 3.9 mm Corkscrew Suture Anchor
<i>Additional Predicate Devices</i>	K101823 – Arthrex SwiveLock Anchors K122374 – Arthrex Suture K193575 – Arthrex SutureTape K171296 – Arthrex SutureTape K170206 – Arthrex FiberTape Cerclage
<i>Purpose of Submission</i>	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex FiberButton.
<i>Device Description</i>	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 Arthrex FiberButton is an oval button made of polyester yarns embroidered over a woven fabric. Suture colorant include D&C Blue No. 6. The Arthrex FiberButton is available in two sizes (10 mm x 6 mm and 14 mm x 8 mm), provided sterile (Ethylene Oxide) for single-use.
<i>Indications for Use</i>	The Arthrex FiberButton is intended for use with Arthrex Suture Anchors and/or Arthrex Suture for orthopedic use.

	<p>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.</p>
<p>Performance Data</p>	<p>To address the risk of tissue pull through, Arthrex conducted testing to ensure the pull through strength of #2 FiberWire suture (additional predicate device K122374) with the support of the Arthrex FiberButton shall be greater than the pull through strength of the #2 FiberWire suture alone. The strength of a suture anchor construct (primary predicate device K193157 and additional predicate device K101823) with the support of the Arthrex FiberButton was evaluated to ensure the strength was equal to or greater than the strength of a suture anchor construct without the Arthrex FiberButton.</p> <p>Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.</p>
<p>Technological Comparison</p>	<p>The materials used in the manufacturing of the proposed Arthrex FiberButton are identical to those used in the legally marketed Arthrex Suture (K122374), Arthrex SutureTape (K171296, K193575) and Arthrex FiberTape Cerclage (K170206) additional predicate devices.</p> <p>The packaging configuration of the proposed FiberButton is the same Double Poly/Tyvek format used for Arthrex Suture (K122374) and Arthrex SutureTape (K171296, K193575) and Arthrex FiberTape Cerclage (K170206) additional predicate devices.</p> <p>Additionally, the proposed Arthrex FiberButton shares the following characteristics with the primary predicate device and additional predicate devices:</p> <ul style="list-style-type: none"> • 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 devices in which the basic design features and intended use are the same. Any differences between the proposed device and the primary and additional predicate devices 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.
