November 26, 2019

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

Re: K191426
Trade/Device Name: FiberTak Button
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 30, 2019
Received: October 31, 2019

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. 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,

Laurence D. Coyne, Ph.D.
Acting 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

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)*

K191426

Device Name

FiberTak Button

Indications for Use *(Describe)*

The FiberTak Button is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures:

• Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

• Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

• Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)

• Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction

• Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

• Hip: Acetabular labral repair

The FiberTak Button is also used for fixation of bone to bone or soft tissue to bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in the knee, shoulder, and elbow and may include the following indications; ACL/PCL repair, pectoralis repair (minor/major), biceps tendon repair and reattachment (distal/proximal), acromioclavicular repair, and ulnar collateral ligament 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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1. 510(k) Summary

Date Prepared	November 25, 2019
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	FiberTak Button
Common Name	Soft Tissue Fixation Device
Product Code	MBI
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	Class II
Predicate Device	K181769: Arthrex FiberTak Suture Anchor K123341: Arthrex Proximal Biceps Button
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the FiberTak Button.
Device Description	The FiberTak Button is an 'all-suture' soft-tissue device constructed from a hollow braid of polyester and two shuttling sutures made of a polyblend of UHMWPE and polyester. The FiberTak Button is preloaded on a disposable inserter and will be sold sterile for single use.
Indications for Use	The FiberTak Button is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip the following procedures: • **Elbow:** Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction • **Shoulder:** Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction • **Hand/Wrist:** Scapholunate Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty) • **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, Digital tendon transfers, Mid-foot reconstruction • **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis • **Hip:** Acetabular Labral Repair The FiberTak Button is also 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 in the knee, shoulder, and elbow and may include the following indications; ACL/PCL repair, Pectoralis Repair (minor/major), Biceps Tendon Repair and Reattachment (distal/proximal), Acromioclavicular Repair, and Ulnar Collateral Ligament Reconstruction.
Performance Data	Tensile testing demonstrated that the pull out strength of the proposed FiberTak Button (including post cyclic loading) met the criteria established by the predicate devices. Biocompatibility testing per ISO 10993-1:2009 demonstrated passing results. Bacterial endotoxin per EP 2.6.14 / USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.

Conclusion	The FiberTak Button is substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate devices are considered minor and do not raise questions concerning safety or effectiveness. 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 devices.