DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 28, 2017

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

Re: K172612
Trade/Device Name: FiberTak DX
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: August 29, 2017
Received: August 31, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172612

Device Name
FiberTak DX

Indications for Use *(Describe)*

FiberTak DX is intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications are listed below:

• 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

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	September 21, 2017
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 DX
Common Name	Soft Tissue Fixation Device
Product Code	MBI
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	K140476: Arthrex FiberTak Suture Anchor
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for a line extension to the Arthrex FiberTak family cleared under K151230.
Device Description	The FiberTak DX is an "all-suture" soft-tissue fixation device. The anchor and connected sutures are impacted into a pilot hole. The sutures are then manually tensioned to set the anchor by "bulging" the suture sleeve within the pilot hole.
Indications for Use	The FiberTak DX is intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications are listed below: • 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
Performance Data	Pull-out testing demonstrated that the pull out displacements of the proposed FiberTak DX met the criteria established by the predicate device. Bacterial endotoxin per EP 2.6.14 / USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Conclusion	The FiberTak DX is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device 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 device.

May 4, 2021

To Whom This May Concern:

In accordance with the regulatory criteria in 21 CFR 807.81(a)(3) and FDA's Guidance *Deciding When to Submit a 510(k) for a Change to an Existing Device*, the differences between the devices cleared via K172612 Arthrex FiberTak DX and the new device (AR-8990ST-2 FiberTak DX Suture Anchor, Double-Loaded With 0.9 mm SutureTape (White/Blue, White) with attached needles) does not meet the threshold for requiring a new premarket notification. Therefore, the new device (AR-8990ST-2 FiberTak DX Suture Anchor, Double-Loaded With 0.9 mm SutureTape (White/Blue, White) with attached needles) is considered cleared via K172612.

Sincerely,

Rebecca R. Homan
Senior Regulatory Affairs Specialist
Arthrex, Inc.