DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 13, 2014

Arthrex, Incorporated
Ms. Courtney Smith
Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108

Re: K140476
Trade/Device Name: Arthrex FiberTak Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 24, 2014
Received: July 28, 2014

Dear Ms. 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 (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 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" (21CFR 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 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 yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.5 INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-01
Expiration Date: December 31, 201
See PRA Statement on last page.

510(k) Number *(if known)*

K140476

Device Name

Arthrex FiberTak Suture Anchor

Indications for Use *(Describe)*

The ***Arthrex FiberTak Suture Anchor*** 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FORM FDA 3881 (9/13) PSC Publishing Services (301) 443-6

2.2 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	April 21, 2014
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Courtney Smith Regulatory Affairs Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: csmith@arthrex.com
Trade Name	***Arthrex FiberTak Suture Anchor***
Common Name	Soft Tissue Fixation Device
Product Code -Classification Name CFR	MBI Fastener, fixation, nondegradable, soft tissue 21 CFR 888.3040
Predicate Device	K112237: Arthrex MicroSuture Anchor
Purpose of Submission	This traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex FiberTak Suture Anchor.
Device Description	The Arthrex FiberTak Suture Anchor is an "all-suture" soft-tissue fixation device with an expandable push-in design. 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. Once the anchor is set, the suture is passed around the soft tissue and tied in a knot to complete the repair. The device is provided sterile intended for single use. The

	anchor is constructed from a hollow braid of polyester. A blue and white striped suture comprised of UHMWPE (white) and Polyester (blue) is assembled through the hollow braid. The striped suture component is designated as TigerWire CL. The device comes preloaded on a disposable inserter. The inserter is made from surgical grade nitinol and ABS plastic. The FiberTak Suture may be sold separately or in a kit with implantation instrumentation.
Intended Use	The ***Arthrex FiberTak Suture Anchor*** 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
Substantial Equivalence Summary	The indications for use of the proposed Arthrex FiberTak Suture Anchor are identical to the predicate device. The submitted mechanical testing demonstrates that the pull-out strength of the proposed devices meets or exceeds the pull-out strength of the predicate devices. Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the FiberTak Suture Anchor is substantially equivalent to currently marketed predicate devices.