



June 22, 2018

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

Re: K180594

Trade/Device Name: Knotless SutureTak Anchors
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: May 23, 2018
Received: May 25, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Sarah B. Nelson -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 AdministrationForm Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.**Indications for Use**

510(k) Number (if known)

K180594

Device Name

Knotless SutureTak Anchors

Indications for Use (Describe)

The Knotless SutureTak Anchors are intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. Specific indications are listed below:

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair

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

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstructions, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital Tendon Transfers

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, Joint Capsule Closure

Hip: Capsular Repair, Acetabular Labral repair

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.**

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1. 510(k) Summary or 510(k) Statement

Date Prepared	June 21, 2018
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	Knotless SutureTak Anchors
Common Name	Suture Anchor
Product Code	MAI, MBI
Classification Name	21 CFR 888.3030: Fastener, Fixation, Biodegradable, Soft Tissue 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	K171020: Arthrex Knotless SutureTak Anchor K101679: Arthrex PushLock Anchors K063478: DePuy Mitek VERSALOK Anchor K140855: Arthrex SutureTak Suture Anchors
Purpose of Submission	This traditional 510(k) premarket notification is submitted to obtain Lateral Epicondylitis Repair indications for the Arthrex Knotless SutureTak Anchor cleared under K171020. This submission also introduces a bioabsorbable version of the cleared Arthrex Knotless SutureTak Anchor.
Device Description	The Knotless SutureTak Anchors are “tap-in” suture anchors with a ribbed profile and a proximally placed external suture eyelet. The anchors are preloaded with Arthrex Suture and are offered preassembled on a driver/insertor, for single use. The Knotless SutureTak Anchors are manufactured from either PEEK or bioabsorbable materials. The PEEK anchor was originally cleared under K120155 for indications in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. The indication for the PEEK anchor was expanded to include Joint Capsule Closure under K171020. The bioabsorbable version of the cleared Arthrex Knotless SutureTak Anchor is made of the same material as the Arthrex PushLock cleared under K101679.
Indications for Use	The Knotless SutureTak Anchors are intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. Specific indications are listed below: • Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair • Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction • Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstructions, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital Tendon Transfers • 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, Joint Capsule Closure • Hip: Capsular Repair, Acetabular Labral repair

<i>Performance Data</i>	Pull-out and degradation testing was conducted to demonstrate that the <i>Knotless SutureTak Anchors</i> perform statistically equivalent to the predicate device. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
<i>Conclusion</i>	The <i>Knotless SutureTak Anchors</i> are substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the subject device and the predicate device are considered minor and do not raise new or different questions of safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed devices are substantially equivalent to the currently marketed predicate device.