



August 30, 2018

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

Re: K181513

Trade/Device Name: Arthrex PushLock Tenodesis Anchor  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: MBI  
Dated: August 1, 2018  
Received: August 3, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -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

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)

K181513

Device Name

Arthrex PushLock Tenodesis Anchor

Indications for Use (Describe)

The Arthrex Tenodesis PushLock Anchor is intended to provide soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue in surgeries of the shoulder, elbow, knee, foot/ankle, and hand/wrist. Specifically;

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

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle

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

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

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/wrist

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

<b>Date Prepared</b>	August 1, 2018
<b>Submitter</b>	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
<b>Contact Person</b>	Ivette Galmez Senior Regulatory Affairs Specialist 1-239-643-5553, ext. 71263 ivette.galmez@arthrex.com
<b>Name of Device</b>	Arthrex PushLock Tenodesis Anchor
<b>Common Name</b>	Soft Tissue Fixation Device
<b>Product Code</b>	MBI
<b>Classification Name</b>	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
<b>Regulatory Class</b>	II
<b>Predicate Device</b>	K051726: Arthrex Tenodesis Family
<b>Reference Predicate</b>	K101679: Arthrex PushLock K101823: SwiveLock Suture Anchors
<b>Purpose of Submission</b>	This Special 510(k) premarket notification is submitted to obtain clearance for the Arthrex PushLock Tenodesis Anchor.
<b>Device Description</b>	The Arthrex PushLock Tenodesis Anchor is a push-in anchor made of Polyetheretherketone. This is the same material of the predicate device. The proposed anchor is designed with either a forked or closed eyelet and comes preloaded on a disposable inserter. These are similar features to the cleared Arthrex PushLock (K101679) and Arthrex SwiveLock (K101823) suture anchors. The proposed anchor is offered sterile.
<b>Indications for Use</b>	The Arthrex Tenodesis PushLock Anchor is intended to provide soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue in surgeries of the shoulder, elbow, knee, foot/ankle, and hand/wrist. Specifically: <ul style="list-style-type: none"> <li>• <b>Shoulder:</b> Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction</li> <li>• <b>Foot/Ankle:</b> Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle</li> <li>• <b>Knee:</b> Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis</li> <li>• <b>Elbow:</b> Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction</li> <li>• <b>Hand/Wrist:</b> Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/wrist</li> </ul>
<b>Performance Data</b>	Tensile testing demonstrated that the pull out strength of the proposed Arthrex PushLock Tenodesis Anchor (including post cyclic loading) 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.
<b>Conclusion</b>	The Arthrex PushLock Tenodesis Anchor is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. 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.