September 13, 2019

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

Re: K190288
Trade/Device Name: Arthrex Tenodesis Button
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: August 9, 2019
Received: August 12, 2019

Dear Ivette 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.
Assistant 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)*

K190288

Device Name

Arthrex Tenodesis Button

Indications for Use *(Describe)*

The Tenodesis Button is used for fixation of bone to bone or soft tissue to bone, and is intended as 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; anterior cruciate ligament, posterior cruciate ligament, 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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510(k) Summary

K190288

Date Prepared	March 26, 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	Arthrex Tenodesis Button
Common Name	Fastener, fixation, nondegradable, soft tissue
Product Code	MBI
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	K123341: Arthrex Pec Repair Button, Large Pec Button, Biceps Button and Proximal Biceps Button
Purpose of Submission	This traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Tenodesis Button. This submission contains a modification to the device labeling to include the "MR Conditional" statement in accordance with the FDA Guidance, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment".
Device Description	The Arthrex Tenodesis Button is made of titanium alloy. The proposed button is preloaded onto a driver/inserter, for single use. The holes in the button allow for the buttons to be threaded with Arthrex non-absorbable suture.
Indications for Use	The Arthrex Tenodesis Button is used for fixation of bone to bone or soft tissue to bone, and is intended as 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; anterior cruciate ligament, posterior cruciate ligament, pectoralis repair (minor/major), biceps tendon repair and reattachment (distal/proximal), acromioclavicular repair, and ulnar collateral ligament reconstruction.
Performance Data	Tensile testing and cyclic loading was conducted to demonstrate that the proposed button performs similar to the predicate device. Non-clinical testing per the FDA Guidance, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", demonstrated that the Arthrex buttons are "MR Conditional". Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Conclusion	The Arthrex Tenodesis Button 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 devices are substantially equivalent to the currently marketed predicate device.