March 26, 2019

Arthrex Inc.
Stacy Valdez
Senior Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K183628
Trade/Device Name: Arthrex TensionLoc™ System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 18, 2018
Received: December 26, 2018

Dear Stacy Valdez:

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) 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183628

Device Name
Arthrex TensionLoc™ System

Indications for Use *(Describe)*
The Arthrex TensionLoc™ System is indicated for fixation of soft tissue, such as tendons and ligaments to bone in orthopedic procedures.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared	December 18, 2018
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Stacy Valdez Senior Regulatory Affairs Associate 1-239-643-5553, ext. 72010 Stacy.valdez@arthrex.com
Name of Device	Arthrex TensionLoc™ System
Common Name	Screw, Fixation, Bone
Product Code	HWC
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	K994202: Acufex® Washer System K151092: Arthrex Short Suture Anchors (Reference) K062466: Interference Screws (Reference) K062747: Arthrex RetroButton (Reference)
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex TensionLoc™ System
Device Description	The Arthrex TensionLoc™ System is a two-component system comprised of a polyetheretherketone (PEEK) plug and a mating collar for suture fixation within a bone tunnel. The primary differences between the Arthrex TensionLoc™ System and the predicate device are the geometry and material. The proposed Arthrex TensionLoc™ System contains a ribbed outer edge collar and plug as opposed to the predicate geometry of a double spiked plate and cannulated post. The Arthrex TensionLoc™ System is also manufactured of PEEK material whereas the predicate is manufactured from titanium. The Arthrex TensionLoc™ System will offer external diameters of 11, 14, and 16 as opposed to the 13-22 mm range of the predicate. The Arthrex TensionLoc™ System is 9.1 mm in length as opposed to the various lengths of the predicate (24-40 mm).
Indications for Use	The Arthrex TensionLoc™ System is indicated for fixation of soft tissue, such as tendons and ligaments to bone in orthopedic procedures.
Performance Data	Cyclic and ultimate load testing was conducted and compared to the predicate device. Biocompatibility testing was conducted in accordance with the requirements of ISO 10993-1 Biological Evaluation of Medical Devices: Evaluation and testing within a risk management process. Sterilization validation has been conducted in accordance with ISO 11135:2014 Sterilization of health-care products – Ethylene Oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices.

	Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Conclusion	The Arthrex TensionLoc™ System is substantially equivalent to the predicate device in which the intended use, sterility, and fundamental scientific technology 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. The submitted mechanical testing data demonstrates that the performance of the proposed devices meets or exceeds the predicate device for the desired indications. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the Arthrex TensionLoc™ System is substantially equivalent to the currently marketed predicate device.