July 30, 2020

Arthrex Inc.
Kelsey Roberts
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108

Re: K201786
Trade/Device Name: Arthrex Mini Hip PushLock
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, HWC
Dated: June 25, 2020
Received: June 30, 2020

Dear Kelsey Roberts:

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,

Laura C. Rose, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201786

Device Name
Arthrex Mini Hip PushLock

Indications for Use *(Describe)*
The Arthrex Mini Hip PushLock is intended to be used for suture (soft tissue) to bone in the hip. Specifically, 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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510(k) Summary
K201786

Date Prepared	July 8, 2020
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Kelsey Roberts Regulatory Affairs Associate 1-239-598-4302, ext. 72257 Kelsey.Roberts@arthrex.com
Name of Device	Arthrex Mini Hip PushLock
Common Name	Smooth or threaded metallic bone fixation fastener
Product Code	MAI, HWC
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances accessories 21 CFR 888.3040: Smooth or threaded metallic bone fastener
Regulatory Class	II
Predicate Device	K151092: Arthrex Short Suture Anchors
Reference Device	K101679: Arthrex PushLock
Purpose of Submission	This Special 510(k) premarket notification is submitted to add the Arthrex 2.4 Mini Hip PushLock as a line extension to the Arthrex Short Anchors cleared under predicate K151092.
Device Description	The Arthrex Mini Hip PushLock is a barbed push-in suture anchor pre-loaded on a disposable inserter. The anchor is manufactured from PLLA/βTCP and is offered sterile, single use.
Indications for Use	The Arthrex Mini Hip PushLock Anchor is intended to be used for suture (soft tissue) fixation to bone in the hip. Specifically, Acetabular Labral Repair.
Comparison Summary of Technological Characteristics and Modifications Proposed	The proposed and predicate devices (K151092) have the same intended use and basic device design. The proposed device modifications consist of anchor material (PLLA/ βTCP) and sterilization method (gamma). The anchor material, manufacturing processes and sterilization method are the same as the reference device (K101679). The Arthrex Mini Hip PushLock Anchor 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 different questions concerning safety or effectiveness.
Performance Data	Pull-out testing was conducted after a 26-week degradation time period and compared to an acceptance criterion of 20 lbf, as established for acetabular labral repair in the predicate submission, demonstrating that the proposed device is substantially equivalent to the predicate device (**K151092**). Biocompatibility testing was not conducted as the materials and processing of the Arthrex Mini Hip PushLock is the same as that of the reference device (**K101679**). Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Conclusion	The proposed Arthrex Mini Hip PushLock Suture Anchor 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 different 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 Arthrex Mini Hip PushLock is substantially equivalent to the currently marketed predicate device.