October 30, 2019

Arthrex Inc.
Heli Chambi Infantas
Senior Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K190921
Trade/Device Name: Arthrex Low Profile Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HRS
Dated: September 27, 2019
Received: September 30, 2019

Dear Heli Chambi Infantas:

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,

Shumaya Ali, M.P.H.
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)*
K190921

Device Name
Arthrex Low Profile Screws

Indications for Use *(Describe)*
The Arthrex Low Profile Screws are intended to be used in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the foot and ankle. The screws may be used with the Arthrex Ankle Fusion Plates.

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

Date Prepared	October 30, 2019
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Heli F Chambi Infantas Senior Regulatory Affairs Associate 1-239-643-5553, ext. 71263 Heli.chambiinfantas@arthrex.com
Name of Device	Arthrex Low Profile Screws
Common Name	Screw, Fixation, Bone Plate, Fixation, Bone
Product Code	HWC, HRS
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	II
Predicate Device	K141735 – Arthrex Ankle Fusion Plating System
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the Arthrex Low Profile screws as a line extension to the Arthrex Ankle Fusion plating System cleared under K141735.
Device Description	The Arthrex Low Profile Screws are headed and self-tapping screws manufactured from Titanium. They are available as fully and solid. The screw family ranges from 4.5 mm to 5.5 mm in diameter and from 80 mm to 120 mm in length (in 5 mm increments). The Arthrex Low Profile Screws are sold as sterile, single-use and non-sterile single-use.
Indications for Use	The Arthrex Low Profile Screws are intended to be used in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the foot and ankle. The screws may be used with the Arthrex Ankle Fusion Plates.
Performance Testing	Arthrex performed driving torque and failure torque/insertion testing to evaluate the potential risk of decrease in mechanical strength. MRI force, torque, and image artifact testing were conducted in accordance with FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*. Bacterial Endotoxins Test (BET) was performed on the Arthrex Low Profile Screws utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14. The testing conducted demonstrates that the Arthrex Low Profile Screws meets pyrogen limit specifications.
Conclusion	The Arthrex Low Profile screws are substantially equivalent to the predicate device in which the basic design features and intended use are the same. Any differences between the Arthrex Low Profile screws and the predicates are considered minor and do not raised different questions concerning safety and effectiveness. 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.