DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2014

Arthrex, Inc.
Ms. Laura Medlin
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108

Re: K141735
Trade/Device Name: Arthrex Ankle Fusion Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC, HTN
Dated: July 18, 2014
Received: July 22, 2014

Dear Ms. Medlin:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141735

Device Name

Arthrex Ankle Fusion Plating System

Indications for Use *(Describe)*

The Arthrex Ankle Fusion Plating System is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, and fibula.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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)*

K141735

Device Name

Arthrex Ankle Fusion Plating System

Indications for Use *(Describe)*

The Arthrex Low Profile Screws (2.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates, Osteotomy Plates, and Ankle Fusion Plating System.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary of Safety and Effectiveness

Date Summary Prepared	August 12, 2014
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Laura Medlin Regulatory Affairs Associate Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 72005 Fax: 239/598.5508 Email: Laura.Medlin@Arthrex.com
Trade Name	***Arthrex Ankle Fusion Plating System***
Common Name	Plate, fixation, bone Screw, fixation, bone
Product Code ***Classification Name / CFR***	HWC, HTN, HRS 21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Predicate Device	K123241: *Arthrex Fracture Plates*
Purpose of Submission	This special 510(k) premarket notification is submitted to obtain clearance for the ***Arthrex Ankle Fusion Plating System***.
Device Description and Intended Use	The ***Arthrex Ankle Fusion Plating System*** is a family of implantable titanium plates and screws intended to be used for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, and fibula. The subject plates are contoured and may be available in

	left and right configurations, ranging in length from 91.9mm to 133.6mm. The accompanying screws are solid or cannulated, fully or partially threaded, and may be locking or non-locking. The proposed screw offering subject of this application are 4.5mm to 6.7mm in diameter and 16mm to 120mm in length and include the partially threaded cannulated lag screws and 13mm washer previously cleared in K123241. The ***Arthrex Low Profile Screws (2.5mm and larger, solid)*** are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex, Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates, Osteotomy Plates, and Ankle Fusion Plating System.
Substantial Equivalence Summary	Based on the intended use, technological characteristics and comparison to the predicate devices, Arthrex, Inc. has determined that the ***Arthrex Ankle Fusion Plating System*** is substantially equivalent to the currently marketed predicate devices, *Arthrex Fracture Plates* (K123241). The implant materials are the same as the predicate devices. Further, mechanical testing data demonstrates that the four-point bending, pull-out and insertion torque strength of the proposed ***Arthrex Ankle Fusion Plating System*** devices are substantially equivalent to or better than the four-point bending, pull-out and insertion torque strength of the predicate devices. Any differences between the ***Arthrex Ankle Fusion Plating System*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness.