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

January 16, 2015

Arthrex, Inc.
David L. Rogers
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K143139
Trade/Device Name: Arthrex Fracture System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: December 15, 2014
Received: December 17, 2014

Dear Mr. Rogers:

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.5 INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-01
Expiration Date: December 31, 201
See PRA Statement on last page.

510(k) Number *(if known)*

K143139

Device Name

Arthrex Fracture System

Indications for Use *(Describe)*

*The **Arthrex Fracture 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, femur, and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.*

*The **Clavicle Plate Button** is intended for use with the clavicle plates for clavicle indications such as for the treatment of syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.*

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)*

FORM FDA 3881 (9/13)

PSC Publishing Services (301) 443-6

K143139

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	January 15, 2015
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	David L Rogers Regulatory Affairs Associate Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 71924 Fax: 239/598.5508 Email: david.rogers@Arthrex.com
Trade Name	**Arthrex Fracture System**
Common Name	Plate, fixation, bone
Product Code -Classification Name ***CFR***	HRS – Plate, Fixation, Bone HWC – Screw, Fixation, Bone 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	*K112437: Arthrex Fracture System*
Purpose of Submission	This **special 510(k)** premarket notification is intended to address the use of Gamma Irradiation and Ethylene Oxide sterilization on the ***Arthrex Fracture System*** devices, which were originally cleared as non-sterile devices under K112437. The intended use, material, and fundamental technological characteristics of the proposed ***Arthrex Fracture System*** are substantially equivalent to the non-sterile predicates.
Device Description	The ***Arthrex Fracture System*** is a family of stainless steel plates, screws, and buttons that will be offered as sterile or non-sterile devices. The plates may be contoured or straight and may be available in left and right configurations. The screw family ranges from 2.7mm to 4.0mm in diameter and from 8mm to 80mm in length. The screws are solid and fully threaded and may be locking or non-locking. The button is stainless steel and designed to fit securely in the holes of the fracture plates. The button is intended to be used

	with the previously cleared suture, which is provided separately.
Intended Use	*The **Arthrex Fracture 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, femur, and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.* *The **Clavicle Plate Button** is intended for use with the clavicle plates for clavicle indications such as for the treatment of syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.*
Substantial Equivalence Summary	The ***Arthrex Fracture System*** is substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the ***Arthrex Fracture System*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The predicate devices are cleared as non-sterile devices. The proposed devices will undergo Gamma Irradiation or Ethylene Oxide (EO) sterilization. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the ***Arthrex Fracture System*** is substantially equivalent to the predicates.