



Food and Drug Administration
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August 28, 2015

Arthrex, Incorporated
Ms. Courtney Smith
Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108

Re: K151732

Trade/Device Name: Arthrex Fracture Plates

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

Dated: June 20, 2015

Received: July 31, 2015

Dear Ms. Smith:

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" (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 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

2.5 INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K151732

Device Name

Arthrex Fracture Plates

Indications for Use *(Describe)*

The ***Arthrex Fracture Plates*** are 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 ***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, and Osteotomy 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)

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)*

2.5 510K SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	August 20, 2015
Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Courtney Smith Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext.71720 Fax: 239/598.5508 Email: Courtney.Smith@Arthrex.com
Trade Name	Arthrex Fracture Plates
Common Name	Plate, fixation, bone
Product Code, Classification Name, CFR	HWC, HRS 21 CFR 888.8030: 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 K141478 - Arthrex Fracture Plates and Screws
Purpose of Submission	This special 510(k) premarket notification is submitted to obtain clearance for Arthrex Fracture Plates and the accompanying screws.
Device Description	The Arthrex Fracture Plates are a family of flat and contoured plates and screws. The plates are comprised of stainless steel and come in a variety of configurations. The Arthrex Fracture Plates are intended to be used with solid locking and non-locking Low Profile Screws. The proposed Low Profile Screws, in this submission, are comprised of Stainless Steel and are 2.7mm in diameter and range from 32mm to 60mm in length.
Intended Use	The Arthrex Fracture Plates are intended to be used for internal bone

	<p>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.</p> <p>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, and Osteotomy Plates.</p>
<p>Substantial Equivalence Summary</p>	<p>The Arthrex Fracture Plates are substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the Arthrex Fracture Plates and the predicates are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>The proposed devices are substantially equivalent to the predicate devices in regards to its intended use, design, size range, and material. The submitted in-vitro testing (4-point bend, section modulus comparison, torque) demonstrates that the performance of the proposed devices is substantially equivalent to that of the predicate devices. The mechanical data indicate that the Arthrex Fracture Plates are adequate for their intended use. Clinical data and conclusions are not needed for this device.</p> <p>Based on the indication for use, technological characteristics, and the comparison to the predicate device, Arthrex, Inc. has determined that the Arthrex Fracture Plates are substantially equivalent to currently marketed predicate devices.</p>