2.1 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 0 3 2013

Date Summary Prepared	May 15, 2013
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Courtney Smith Regulatory Affairs Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: csmith@arthrex.com
Trade Name	***Arthrex Distal Radius Plate System***
Common Name	Plate, fixation, bone Screw, fixation, bone
Product Code -Classification Name ***CFR***	HRS Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3030 HWC Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040
Predicate Device	*K040022 / K100271: Stryker VariAx Distal Radius Locking Plate System* *K123875: aap Radius Set* *K103705 / 111253: Low Profile Screws*
Purpose of Submission	This traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Distal Radius Plate System.
Device Description	The Arthrex Distal Radius Plate System is a family of plates offered in various widths, thicknesses and lengths and

	locking screws in various diameters and lengths.
Intended Use	The Distal Radius Plate System is intended for internal fixation for fractures and reconstruction of the small bones, primarily including the distal radius and distal ulna. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and malunions. This system can be used for palmar, dorsal or orthogonal application. The Arthrex Low Profile Screws (2.0-2.4mm 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. When used with a plate, the screw may be used with the Arthrex Low Profile, Small Fragment Plates, Distal Extremity Plates, and Distal Radius Plates. The Arthrex Low Profile Screws (2.0-3.0mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist. The Arthrex Low Profile Screws (2.7mm 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, Distal Radius Plates, Humeral Fracture Plates, and Osteotomy Plates. The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws 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.
Substantial Equivalence Summary	The Arthrex Distal Radius Plate 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 Distal Radius Plate System and the predicates are considered minor and do not raise questions concerning safety and effectiveness.

	The proposed devices are comprised of titanium. This material is substantially equivalent to the materials found in the predicate devices. The submitted mechanical testing data demonstrates that the bending strength and the fatigue strength of the proposed devices are comparable to that of the predicate device for the desired indications. Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the Distal Radius Plate System is substantially equivalent to currently marketed predicate devices.

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

July 3, 2013

Arthrex, Incorporated
% Ms. Courtney Smith
Regulatory Affairs Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K131474
Trade/Device Name: Arthrex Distal Radius Plate 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
Dated: May 31, 2013
Received: June 3, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Erin D Keith

For

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

Enclosure

2.1 INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K131474 page 1 of 2

Device Name: **Arthrex Distal Radius Plate System**

Indications For Use:

The ***Arthrex Distal Radius Plate System*** is intended for internal fixation for fractures and reconstruction of the small bones, primarily including the distal radius and distal ulna. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and malunions.

This system can be used for palmar, dorsal or orthogonal application.

Prescription Use _✓_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth A. Frank -S

Division of Orthopedic Devices

Indications for Use

510(k) Number (if known): K131474 page 2 of 2

Device Name: **Arthrex Low Profile Screws**

Indications For Use:

The Arthrex Low Profile Screws (2.0-2.4mm 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. When used with a plate, the screw may be used with the Arthrex Low Profile, Small Fragment Plates, Distal Extremity Plates, and Distal Radius Plates.

The Arthrex Low Profile Screws (2.0-3.0mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist.

The Arthrex Low Profile Screws (2.7mm 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, Distal Radius Plates, Humeral Fracture Plates, and Osteotomy Plates.

The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws 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.

Prescription Use _✓_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Orthopedic Devices