2.5 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	February 5, 2015
Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Laura Medlin Regulatory Affairs 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 Distal Radius System***
Common Name	Plate, fixation, bone Screw, fixation, bone
Product Code, Classification Name	HRS – Plate, Fixation, Bone HWC – Screw, Fixation, Bone
CFR	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	K082300: *DePuy Orthopaedics Anatomic Locking Plating System* K081546: *DePuy Orthopaedics Small Bone Locking Plating System* K131474: *Arthrex Distal Radius Plate System* K040907: *Arthrex Small Fragment Plates and Screws*
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to obtain clearance for the ***Arthrex Distal Radius System***.
Device Description	The ***Arthrex Distal Radius System*** is a family of implantable titanium plates and screws intended to be used for fixation of fractures, fusions, osteotomies and non-unions of the radius, ulna, olecranon, metacarpal, metatarsal, and malleolus. The subject plates are contoured and may be available in left and right configurations, ranging in length from 25mm to 166mm and feature both locking and non-locking holes. The accompanying screws are solid, fully or partially threaded, and may be locking or non-locking. The proposed screw offering subject of this application are 2.4mm to 3.5mm in diameter and 8mm to 34mm in length and include the *Arthrex Low Profile Screws* previously cleared under the auspices of K131474.
Intended Use	The ***Arthrex Distal Radius System*** is intended for fixation of fractures, fusions, osteotomies and non-unions of the radius, ulna, olecranon, metacarpal, metatarsal, and malleolus.
Substantial Equivalence Summary	The ***Arthrex Distal Radius 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 System*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The submitted mechanical testing data demonstrates that the bending strength of the plates is substantially equivalent to that of the predicate devices. Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the ***Arthrex Distal Radius System*** is substantially equivalent to currently marketed predicate devices.

2.4 INDICATIONS FOR USE

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)*
K143749

Device Name
Arthrex Distal Radius System

Indications for Use *(Describe)*
The Arthrex Distal Radius System is intended for fixation of fractures, fusions, osteotomies and non-unions of the radius, ulna, olecranon, metacarpal, metatarsal, and malleolus.

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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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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

April 3, 2015

Arthrex Inc.
Ms. Laura Medlin
Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K143749
Trade/Device Name: Arthrex Distal Radius 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: February 5, 2015
Received: February 11, 2015

Dear Ms. Laura 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,

Mark N. Melkerson -S

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

Enclosure