



Food and Drug Administration  
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Silver Spring, MD 20993-0002

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

May 15, 2015

Re: K151078

Trade/Device Name: Arthrex RetroFusion Screw  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener  
Regulatory Class: Class II  
Product Code: HWC  
Dated: April 20, 2015  
Received: April 22, 2015

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" (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,

**Mark N. Melkerson -S**

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

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)

K151078

Device Name

Arthrex RetroFusion Screw

Indications for Use (Describe)

The Arthrex RetroFusion Screw is intended to fix small bony or apical chondral fragments in the foot, ankle, upper extremities, hand, and wrist, where such fragments are not under tension or load-bearing. These devices are used in cases of osteochondritis dissecans and osteochondral fragments, fixation of fractures, 1st metatarsal (bunionectomy osteotomies), cuneiform bones, inherently stable osteotomies, and fusions of the phalanges, metatarsals, metacarpals, carpal bones, tarsal bones, ankle, and wrist. The devices can be used for inherently stable intramedullary stabilization of joint arthroplasty (resection) or fusion for the treatment of digital deformities of the foot or hand. This device is also used in inherently stable long bone fractures such as the femur, fibula, tibia, radius and ulna, including the diaphyseal, epiphyseal, and metaphyseal areas.

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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2.6 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS	
<b><i>Date Summary Prepared</i></b>	April 20, 2015
<b><i>Manufacturer/Distributor/Sponsor</i></b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b><i>510(k) Contact</i></b>	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
<b><i>Trade Name</i></b>	<b>Arthrex RetroFusion Screw</b>
<b><i>Common Name</i></b>	Screw
<b><i>Product Code -Classification Name</i></b>	HWC – Screw, Fixation, Bone
<b><i>CFR</i></b>	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
<b><i>Predicate Device</i></b>	K050259: Arthrex Bio-Pin
<b><i>Purpose of Submission</i></b>	This special 510(k) premarket notification is submitted to obtain FDA clearance for the <b>Arthrex RetroFusion Screw</b> .
<b><i>Device Description</i></b>	The <b>Arthrex RetroFusion Screw</b> is an implant with a dual threaded design and ranges in size from 20 to 32mm in length. The RetroFusion screw is inserted between the proximal and middle phalanges, so the opposing threads fixate on the phalangeal canal of the toe and compress the joint.
<b><i>Intended Use</i></b>	The <b>Arthrex RetroFusion Screw</b> is intended to fix small bony or apical chondral fragments in the foot, ankle, upper extremities, hand, and wrist, where such fragments are not under tension or load-bearing. These devices are used in cases of osteochondritis dissecans and osteochondral fragments, fixation of fractures, 1st metatarsal (bunionectomy osteotomies), cuneiform bones, inherently stable osteotomies, and fusions of the phalanges, metatarsals, metacarpals, carpal bones, tarsal bones, ankle, and wrist. The devices can be used for inherently stable intramedullary stabilization of joint

	<p>arthroplasty (resection) or fusion for the treatment of digital deformities of the foot or hand. This device is also used in inherently stable long bone fractures such as the femur, fibula, tibia, radius and ulna, including the diaphyseal, epiphyseal, and metaphyseal areas.</p>
<p><b><i>Substantial Equivalence Summary</i></b></p>	<p>The <b><i>Arthrex RetroFusion Screw</i></b> is substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the <b><i>Arthrex RetroFusion Screw</i></b> and the predicate are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>Pull-out testing demonstrates that the pull-out strength of the <b><i>Arthrex RetroFusion Screw</i></b> is significantly greater than the predicate.</p> <p>Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the <b><i>Arthrex RetroFusion Screw</i></b> is substantially equivalent to the predicates.</p>