2.1 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	August 26, 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 Compression FT Screws***
Common Name	Screw, fixation, bone
Product Code -Classification Name ***CFR***	HWC Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040
Predicate Device	K060478: Arthrex Bio-Compression Screw K103705: Arthrex Low Profile Screws
Purpose of Submission	This traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Compression FT Screws.
Device Description	The Arthrex Compression FT Screws are a family of screws designed to provide fixation of fractures, osteotomies and arthrodesis. These titanium screws are cannulated with a tapering head. The screws will be offered in three diameters, 2.8mm, 3.7mm and 4.1mm, and will range in length from 8mm to 50mm.
Intended Use	The Arthrex Compression FT Screws is intended for fixation of small bone fragments, such as apical fragments, osteochondral fragments and cancellous

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	fragments. Specific applications include the following: • Osteochondral fragments (talar vault, femoral condyle) • apical fragments (radial head, patellar rim, navicular, metacarpal/metatarsal) • cancellous fragments (talus) • Carpal, metacarpal, and small hand bone • tarsal and metatarsals • phalanges • Intra-articular fractures • ankle • proximal and distal humerus • proximal and distal radius • proximal and distal ulna • osteochondral fixation and fractures • Osteochondritis Dissecans • Fixation of fractures and osteotomies about the knee • Oblique fractures of the fibula • Reconstructive surgeries of the foot • malleolar fixation
Substantial Equivalence Summary	The Arthrex Compression FT Screws is substantially equivalent to the predicate devices, in which the basic design features and intended uses are the same. Any differences between the Arthrex Compression FT Screws 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 (insertion, pull-out and compression) data demonstrates that the proposed devices are substantially equivalent to that of the predicate device. Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the Compression FT

	Screws 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

November 25, 2013

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

Re: K132217
Trade/Device Name: Arthrex Compression FT Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 28, 2013
Received: October 30, 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,

Mark N. Melkerson -S

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): K132217

Device Name: **Arthrex Compression FT Screws**

Indications For Use:

The Arthrex Compression Screw is intended for fixation of small bone fragments, such as apical fragments, osteochondral fragments and cancellous fragments. Specific applications include the following:

- Osteochondral fragments (talar vault, femoral condyle)
- apical fragments (radial head, patellar rim, navicular, metacarpal/metatarsal)
- cancellous fragments (talus)
- Carpal, metacarpal, and small hand bone
- tarsal and metatarsals
- phalanges
- Intra-articular fractures
- ankle
- proximal and distal humerus
- proximal and distal radius
- proximal and distal ulna
- osteochondral fixation and fractures
- Osteochondritis Dissecans
- Fixation of fractures and osteotomies about the knee
- Oblique fractures of the fibula
- Reconstructive surgeries of the foot
- malleolar fixation

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)

Elizabeth L. Frank -S

Division of Orthopedic Devices