MAR 1 8 2011

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1 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	March 10, 2011
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Courtney Smith Regulatory Affairs Project 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	***Low Profile Screws***
Common Name	Screw, fixation, bone
Product Code -Classification Name CFR	HWC, HRS 21CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener.
Predicate Device	*K052614*: Arthrex Low Profile Plate and Screw System *K062863*: Osteomed Extended 2.0/2.4 Cannulated Screw System *K001941*: Synthes Modular Foot System *K043185*: Synthes 3.5mm Cortex Screws *K102343*: Cannulated Screw System
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to obtain clearance for the Low Profile Screws. The ***Arthrex Low Profile Screws*** are a line extension of the Low Profile Screws cleared in K052614.
Device Description and Intended Use	The Arthrex ***Low Profile Screw*** is fully or partially threaded, titanium or stainless steel, self-tapping, headed screw. The screw ranges from 2.0 mm to 4.0 mm in diameter and in length from 8 mm to 80 mm. The screw may be either solid or cannulated. The ***Arthrex Low Profile Screws (2.0-3.0mm 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 and Small Fragment Plates.

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	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 (3.5mm 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 and Small Fragment 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 ***Low Profile Screws*** are substantially equivalent to the predicate Osteomed Extended 2.0/2.4 Cannulated Screw System, Synthes Modular Foot System, Synthes 3.5mm Cortex Screw, and the previously cleared Arthrex Low Profile Screws, in which the basic features and intended uses are the same. Any differences between the ***Low Profile Screws*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The proposed devices are composed of Titanium or Stainless Steel that is substantially equivalent to the predicate devices. The submitted mechanical testing data demonstrated that the torque and pull-out force of the proposed devices is substantially equivalent to the torque and pull-out force of the predicate devices. Based on the indication for use, technological characteristics, and the comparison to the predicate devices, Arthrex, Inc. has determined that the ***Low Profile Screws*** are substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Inc.
% Ms. Courtney Smith
1370 Creekside Boulevard
Naples, Florida 34108-1945

MAR 18 2011

Re: K103705
Trade/Device Name: Arthrex Low Profile Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, HRS
Dated: February 16, 2011
Received: February 18, 2011

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.

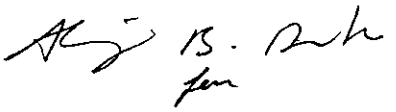
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indications for Use Form

Indications for Use

510(k) Number (if known): K103705

Device Name: ***Arthrex Low Profile Screws***

Indications For Use:

The Arthrex Low Profile Screws (2.0-3.0mm 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 and Small Fragment 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 (3.5mm 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 and Small Fragment 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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for M. Nuttern

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103705