K081011 P. 1/2

AREXUSA

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NOV - 7 2008

PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.93)

Date of Preparation: April 7, 2008

Applicant:	AREX USA LLC 1335 Merrybrook Rd. Collegeville, PA 19403
Contact Individual:	Ellen Hokanson, President 610-584-6870
Trade Name:	AREX SCRU 2 Headless Compression Screw
Common Name:	Cannulated Compression Screw
Regulation:	888.3040
Product Code:	HWC
Classification Name:	Pin, Fixation Threaded
Classification:	Class II
Predicate Device Name:	Zimmer Herbert Bone Screw (K792022) Synthes Cannulated Screw System (K050636)
Device Description:	The AREX SCRU 2 Headless Compression Screws are cannulated, self drilling, self tapping, dual-pitch threaded devices which can be countersunk into the bone. The screw is available in titanium alloy with and OD of 2.5 or 3 mm and lengths from 10mm up to 45 mm, in increments of 5 mm. The screws are supplied non-sterile.

Intended Use:	The AREX SCRU2 headless compression screw is intended for fixation of intra-articular and extra-articular fractures of the upper and lower extremities, as well as non-unions of small bones and bone fragments, arthrodesis of small joints, bunionectomies and osteotomies. Examples include scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.
Technology Characteristics:	The design, materials and indications for use of the AREX SCRU 2 headless compression screws are equivalent to devices previously approved for market in the United States.
Conclusion:	The design, materials and indications for use demonstrate that the AREX SCRU 2 headless compression screws are substantially equivalent to the predicate devices, and safe and effective for use, when used in accordance with the supplied instructions for use.

11/7/08

Ellen Hokanson Date
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arex USA LLC
% Ms. Ellen Hokanson
President
1335 Merrybrook Road
Collegeville, Pennsylvania 19403

NOV - 7 2008

Re: K081011
Trade/Device Name: Arex SCRU 2 Headless Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 21, 2008
Received: October 22, 2008

Dear Ms. Hokanson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510K Number: K081011

Device Name: AREX SCRU2 Headless Compression Screw

Indications for Use:

The AREX SCRU2 headless compression screw is intended for fixation of intra-articular and extra-articular fractures of the upper and lower extremities, as well as non-unions of small bones and bone fragments, arthrodesis of small joints, bunionectomies and osteotomies. Examples include scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

Prescription Use ___X____ AND/OR Over-The-Counter Use No

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K081011