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FEB 1 8 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Arthrex Bi-Cortical Bio-Post™ and Washers

MANUFACTURER / SPONSOR

Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

510(K) CONTACT:

Sally Foust, RAC
Sr. Regulatory Affairs Specialist
Telephone: (239) 643-5553 ext. 1251
FAX: (239) 598-5539

TRADE NAME:

Bi-Cortical Bio-Post™ and Washers

COMMON NAME:

Fastener
Washer, Bolt, Nut
Screw, Fixation, Bone

PRODUCT CODE / CLASSIFICATION NAME

Fastener, Fixation, Biodegradable, Soft Tissue

21 CFR 888.3030 / HTN
Single/multiple component metallic bone fixation appliances and accessories

21 CFR 888.3040 / HWC
Fastener, Fixation, Nondegradable, Soft Tissue
Smooth or threaded metallic bone fixation fastener

PREDICATE DEVICES:

K023119, Bi-Cortical Bio-Post™ and Washers
K011495, Bio-Post™ and Washers
K021932, 6.5 mm Cannulated Screw
K012001, SmartScrew™
K030900, OTPS™ Biodegradable Fixation System

DEVICE DESCRIPTION AND INTENDED USE:

The Arthrex Bi-Cortical Bio-Post™ and Washers device is a PLLA 6.5 mm diameter x 70 mm length post screw with a hybrid thread and two 16mm washers in two configurations, smooth and spiked.

The Arthrex Bi-Cortical Bio-Post™ and Washers device is intended as an anchor device for suture or to secure soft tissue directly to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow.

The Arthrex Bi-Cortical Bio-Post™ and Washers device is intended for the maintenance of alignment, reduction, and fixation of fractures, osteotomies or arthrodesis of the upper extremity, ankle and foot, or condylar grafts.

SUBSTANTIAL EQUIVALENCE SUMMARY

The Arthrex Bi-Cortical Bio-Post™ and Washers device is substantially equivalent to the predicate devices where basic features and intended uses are the same. Any differences between the Arthrex Bi-Cortical Bio-Post™ and Washers and the predicate devices are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the Bi-Cortical Bio-Post™ and Washers are substantially equivalent to the currently marketed predicate devices cleared for the expanded indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Ms. Sally Foust, RAC
Sr. Regulatory Affairs Specialist
Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108

Re: K043145
Trade/Device Name: Arthrex Bi-Cortical Bio-Post™ and Washers
Regulation Number: 21 CFR 888.3030, 21 CFR 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTN, HWC
Dated: February 7, 2005
Received: February 9, 2005

Dear Ms. Foust:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043145

Device Name: Arthrex Bi-Cortical Bio-Post™ and Washers

Indications for Use:

1) The Arthrex Bi-Cortical Bio-Post™ and Washers device is intended as an anchor device for suture or to secure soft tissue directly to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow in the following procedures:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Reconstruction, Midfoot Reconstruction.

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Illiotibial Band Tenodesis.

Hand/Wrist: Scaphaolunate Ligament Reconstruction, Ulnar Collateral Ligament Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

2) The Arthrex Bi-Cortical Bio-Post™ and Washers device is intended for the maintenance of alignment, reduction, and fixation of fractures, osteotomies or arthrodesis of the upper extremity, ankle and foot.

Fusions/fracture of Phalangeal, Metacarpal, and Carpal
Wrist arthrodesis
Fractures of Distal radius, Olecranon, Radial head, Humeral condylar, Cancellous
Osteotomies Malleolus, Ankle fractures, Metatarsal
Correction of hallux valgus

Prescription Use 21e AND/OR Over-The-Counter Use No
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

for Mark N. Milhous
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K043145