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510(k) Summary

MAR 06 2007

510(k) Number:

Company: Arthrex, Inc.
Address: 1370 Creekside Blvd., Naples, FL 34108-1945
Telephone: (239) 643-5553
Facsimile: (239) 598-5508
Contact: Ann Waterhouse, RAC

Device Name: Arthrex CrossPin™
Classification: Screw, Fixation, Bone
Product Code: HWC (21 CFR 888.3040)
MAI (21 CFR 888.3030)

Description:

The Arthrex CrossPin™ is a sterile, disposable device designed for single patient use only. The Cross Pin™ is constructed of an enhanced polymer, Poly(L-lactide) or PLLA.

Predicate Device;

K010633, Mitek Products RigidFix Tibial ACL Cross Pin System

Indications for Use:

The Arthrex CrossPin™ is intended to be used for tibial fixation of autograft or allograft ACL soft tissue grafts.

Substantial Equivalence Summary

The Arthrex CrossPin™ is substantially equivalent to the predicate Mitek Product RigidFix Tibial ACL Cross Pin System in which the basic features and intended uses are the same. Minor differences between the Arthrex CrossPin™ and the predicate device do not raise any questions concerning safety and effectiveness and have no apparent effect on the performance, function, or intended use of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 06 2007

Arthrex, Inc.
% Ms. Ann Waterhouse, RAC
Regulatory Affairs Project Manager
1370 Creekside Blvd.
Naples, FL 34108-1945

Re: K063719
Trade/Device Name: Arthrex CrossPin™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY, HWC
Dated: December 14, 2006
Received: December 15, 2006

Dear Ms. Waterhouse:

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.

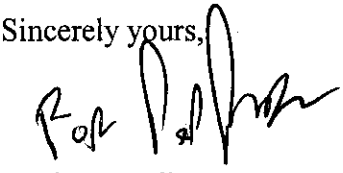
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (21 CFR Part 807.97). 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 240-276-3150 or at its 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

K063719

Indications for Use

Device Name: Arthrex CrossPin™

Indications for Use:

The Arthrex CrossPin™ is intended to be used for tibial fixation of autograft or allograft ACL soft tissue grafts.

Prescription Use ___X____ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (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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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063719