DEC 1 8 2002 K023119

510(k) Summary

510(k) Number:
Contact Person: Ann Waterhouse, Regulatory Affairs Specialist
Date Prepared: September 11, 2002

Trade/Proprietary Name: Bi-Cortical Bio-Post and Washer
Product Code: ~~MAT~~ HTN/HWC
Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue
Predicate Devices: Arthrex, Inc. Bio-Post and Washer System, Synthes(USA), Synthes Bioresorbable Suture Anchor, Bionx Implants, LTD., Smartwedge ACL, Bionx Implants, LTD>, Smart Screw ACL, Bionx Implants, LTD., Biocuff.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Intended Use:

The Bi-Cortical Bio-Post and Washer is intended as an anchor device for suture or to secure soft tissue directly to bone.

Description:

Arthrex, Inc. Bio-Post and Washer is intended for suture fixation or securing soft tissue to bone. The Bio-Post and Washer is composed of poly(l-lactide) acid, PLLA which is biodegradable and biocompatible. It is 35 mm in length and 6.5 mm wide at the head of the Bio-Post. The addition of the washer increases the diameter to 16.5 mm.

Substantial Equivalence:

The Arthrex, Inc. Bio-Post and Washer is substantially equivalent to predicate devices where the basic features and intended uses are the same. Minor differences between the Arthrex Bio-Post and Washer and predicate devices 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

DEC 18 2002

Ms. Ann Waterhouse
Regulatory Affairs Specialist
Arthrex, Inc.
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K023119
Trade/Device Name: Bi-Cortical Bio-Post and Washer™
Regulation Number: 21 CFR 888.3030 and 21 CFR 888.3040
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories; and Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTN and HWC
Dated: September 18, 2002
Received: September 19, 2002

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for 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

510(k) Number (if known): K023119

Device Name: **Arthrex Bio-Post and Washer**

Indications for Use:

The Arthrex Bio-Post and Washer is intended as an anchor device for suture or to secure soft tissue directly to bone.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Option Format 3-10-98)

Miriam C. Provost

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

510(k) Number K023119