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K031666
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510(k) Summary

510(k) Number: **K031666**
Contact Person: Ann Waterhouse, Regulatory Affairs Specialist
Date Prepared: June 2003

Trade/Proprietary Name: Arthrex ACL RetroConstruction™ Button Kit
Product Code: HRS
Classification Name: Plate, Fixation, Bone
Predicate Devices: Arthrex K010673, Arthrex K012923, Arthrex K021434, Smith & Nephew K980155, Karl Storz Endoscopy-America, Inc. K022853, DePuy ACE K990120, DePuy ACE K982347, and Bonutti Research K990156.

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 Arthrex ACL RetroConstruction™ Button Kit for fixation of bone to bone or soft tissue to bone is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair utilizing titanium buttons and recommending use of size 2 or size 5 FiberWire™ or equivalent. Specifically, Arthrex will be offering this for ACL repair.

Description:

Arthrex, Inc. ACL RetroConstruction™ Button Kit consists of metal buttons. These buttons are Titanium 6AL4V ELI and have either 2 or 4 holes for inclusion of suture. The suture recommended for use with this kit is FiberWire™, an Arthrex product, which is offered in various sizes and configurations.

Substantial Equivalence:

The Arthrex, Inc. ACL RetroConstruction ™ Button kit is substantially equivalent to predicate devices where the basic features and intended uses are the same. Minor differences between the Arthrex device 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

NOV 18 2003

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

Re: K031666
Trade/Device Name: Arthrex Fiberwire™ Button Repair Kit
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: HRS, GAT
Dated: September 25, 2003
Received: September 26, 2003

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.

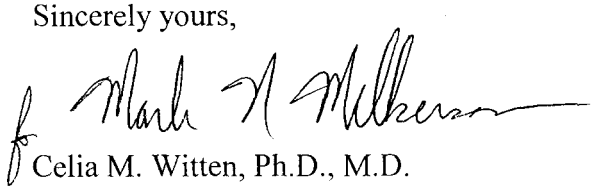
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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): K031666

Device Name: **Arthrex Fiberwire™ Button Repair Kit**

Indications for Use:

The Arthrex ACL RetroConstruction™ Button Kit for fixation of bone to bone or soft tissue to bone is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair utilizing titanium buttons and recommending use of size 2 or size 5 FiberWire™ or equivalent. Specifically, Arthrex will be offering this for ACL repair.

(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)

for Mark N Milhern

Division Sign-Off

Division of General, Restorative and Neurological Devices

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