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VIII. 510(k) Summary of Safety and Effectiveness

Arthrex RetroButton™

Manufacturer / Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, Florida 34108-1945
510(k) Contact:	Ann Waterhouse, RAC Regulatory Affairs Project Manager Telephone: (239) 643-5553 ext. 1179 FAX: (239) 598-5508
Trade Name:	Arthrex RetroButton™
Common Name:	Plate, fixation, bone Suture, synthetic, nonabsorbable, polyethylene or silk
Product Code / Classification Name:	HRS, 21 CFR 888.3030 Plate, Fixation, bone GAT, 21 CFR 878.5000 Suture, synthetic, nonabsorbable, polyethylene GAP, 21 CFG 878.5030 Suture, nonabsorbable, silk
Predicate Device:	Arthrex FiberWire® Button Repair Kit, K031666

SEP 29 2006

Device Description and Intended Use:
The Arthrex RetroButton™ is a pre-threaded button construct.

The Arthrex RetroButton™ for fixation of bone to bone or soft tissue to bone, and is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering this for Anterior Cruciate Ligament (ACL) Repair.

Substantial Equivalence:
The Arthrex RetroButton™ is substantially equivalent to the predicate Arthrex FiberWire® Button Repair Kit in which the basic features and intended uses are the same. Any differences between the Arthrex RetroButton™ and the predicate are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the RetroButton™ is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

SEP 29 2006

Re: K062747
Trade/Device Name: ~~Arthrex~~ RetroButton™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, GAT, GAP
Dated: September 13, 2006
Received: September 14, 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" (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 (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

III. Indications for Use Form

510(k) Number (if known): K062747

Device Name: Arthrex RetroButton™

Indications for Use:

The Arthrex RetroButton™ for fixation of bone to bone or soft tissue to bone, and is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering this for Anterior Cruciate Ligament (ACL) Repair.

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)

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

510(k) Number K062747