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3 510(k) Summary of Safety and Effectiveness

Table 1 510(k) Summary of Safety and Effectiveness

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 Email: awaterhouse@arthrex.com
Trade Name	Meniscal Cinch
Common Name	Suture, non-degradable, Fastener, Fixation, non-degradable soft tissue
Product Code	GAT MBI
Predicate Devices	K072322, Smith & Nephew ULTRA FAST-FIX & ULTRA FAST-FIX AB Meniscal Repair Systems
Device Description and Intended Use	The Arthrex Meniscal Cinch is an implantable suture retention device consisting of FiberWire suture and small PEEK tubes. The FiberWire suture is offered in a #2-0 size. The Arthrex Meniscal Cinch is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including the repair of meniscal tears.
Substantial Equivalence Summary	Testing of the Arthrex Meniscal Cinch compared to that of the predicate K072322 FAST-Fix support the common functionality and intended use as well as substantial equivalence of the device. The Arthrex Meniscal Cinch is substantially equivalent to predicate devices where the basic features and intended uses are the same. Minor differences between the Arthrex Meniscal Cinch and the predicate device do not raise any questions concerning safety and effectiveness and has no apparent effect on the performance, function, or intended use of this device.

FEB 11

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2008

Arthrex, Inc.
% Ms. Ann Waterhouse
1370 Creekside Blvd.
Naples, FL 34108

Re: K073149
Trade/Device Name: Arthrex Meniscal Cinch
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT, MBI
Dated: February 4, 2008
Received: February 5, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Indications for Use

510(k) Number: K073149
Device Name: Arthrex Meniscal Cinch

The Arthrex Meniscal Cinch is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including the repair of meniscal tears.

Prescription Use _✓_ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (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 K073149