AUG - 5 2004

510(k) Summary

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510(k) Number: **K041589**
Contact Person: Ann Waterhouse, Regulatory Affairs Specialist
Sponsor: Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108
Date Prepared: June 2004

Trade/Proprietary Name: Arthrex FiberWire® Family
Product Code: GAT, GAP, GAW
Classification Name: Suture, Non-absorbable, Synthetic, Polyester and Silk
Predicate Devices: Arthrex K021434, Johnson & Johnson K012124, AuroLab K024091

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 Fiberwire® Family is intended for use in soft tissue approximation and or ligation including allograft tissue.

Description:

Arthrex Fiberwire® and FiberTape™ sutures of varying lengths, diameters, and needle types are made of long chain polyesters, braided with nylon or silk, and sterilized for surgical use. They are available in dyed and non-dyed varieties, with or without needles.

Technical Differences in Regards to Predicate Devices:

The Arthrex FiberWire Family is made up of several sutures which have similar or identical material make up. The difference in the predicate K021434 Arthrex FiberWire Family of sutures, when compared to the subject of this submission, consists of a marker thread of silk instead of nylon.

Substantial Equivalence:

The Arthrex, Inc. FiberWire™ Family of sutures is substantially equivalent to predicate devices where the basic features and intended uses are the same. Minor differences between the Arthrex suture products and the predicate devices do not raise any questions concerning safety and effectiveness and have no apparent effect on the performance, function, or intended use of these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 2004

Ms. Ann Waterhouse
Senior Regulatory Affairs Specialist
Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K041589
Trade/Device Name: Arthrex FiberWire
Regulation Number: 21 CFR 878.5000
Regulation Name: Non-absorbable polyethylene terephthalate surgical suture
Regulatory Class: II
Product Code: GAT
Dated: June 10, 2004
Received: June 11, 2004

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,

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): K041589

Device Name: **Arthrex FiberWire™**

Indications for Use:

The Arthrex Fiberwire™ and FiberTape™ Families are intended for use in soft tissue approximation and/or ligation including allograft tissue.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K041589