

K012923

OCT - 4 2001

510(k) Summary

510(k) Number:

Contact Person: Ann Waterhouse, Regulatory Affairs Specialist

Date Prepared: August 29, 2001

Trade/Proprietary Name: Arthrex Fiberwire™ USP size 5 suture

Product Code: GAT

Classification Name: Suturum Nonabsorbable, Synthetic, Polyester

Predicate Devices: Arthrex, K010673, Grams American Suture, K003590, Aesculap, Inc., K990088, ARC Medical Supplies, K000540, Genzyme Surgical Product, K001434, and C.P. Medical, K001172

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™ USP size 5 suture is intended for use in soft tissue approximation and or ligation.

Description:

Arthrex, Inc. Fiberwire™ suture is 38 " in length and has a diameter of 0.700 to 0.799 mm. It is made of long chain polyesters which are braided and sterilized and for surgical use. It is available in dyed and non-dyed varieties, with or without needles.

Substantial Equivalence:

The Arthrex, Inc. Fiberwire™ USP size 5 suture is substantially equivalent to predicate devices where the basic features and intended uses are the same. Minor differences between the Arthrex suture 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.

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OCT - 4 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K012923
Trade/Device Name: Arthrex Fiberwire™ USP Size 5 Suture
Regulation Number: 878.5000
Regulation Name: Nonabsorbable Poly (ethylene terephthalate) Surgical Suture
Regulatory Class: II
Product Code: GAT
Dated: August 28, 2001
Received: August 31, 2001

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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,



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): K012923

Device Name: **Arthrex Fiberwire™, USP size 5**

Indications for Use:

The Arthrex Fiberwire™ USP size 5 suture is intended for use in soft tissue approximation and or ligation.

(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)



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

510(k) Number K012923 CC0088