JAN 1 4 2004

K032245

510(k) Summary

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

Trade/Proprietary Name: Arthrex FiberTape™ Family
Product Code: GAT
Classification Name: Suture, Non-absorbable, Synthetic, Polyester
Predicate Devices: Arthrex K010673, Arthrex K012923, Arthrex K021434, Johnson & Johnson K012124, and Ethicon Endo-Surgery Mersilene Tape.

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 FiberTape™ Family suture products, like it's predecessor the FiberWire Family, are intended for use in approximation and/or ligation of soft tissue, including use of allograft tissue for orthopedic surgeries.

Description:

Arthrex, Inc. FiberTape™ Family consists is a ribbon-like suture consisting of FiberWire components along with several needle types for specific surgical uses. These "tapes" are made of long chain polyesters which are braided and sterilized for surgical use. They are available in dyed and non-dyed varieties, with or without needles.

Substantial Equivalence:

The Arthrex, Inc. FiberTape™ Family is substantially equivalent to predicate devices where the basic features and intended uses are the same. Minor differences between the Arthrex suture tape 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

JAN 1 4 2004

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

Re: K032245
Trade/Device Name: Arthrex FiberTape™ Family
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(ethylene) Terephthalate Surgical Suture
Regulatory Class: II
Product Code: GAT
Dated: October 14, 2003
Received: October 16, 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling following the indications for use:

> The safety and effectiveness of this device for use as an artificial ligament or tendon has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-___. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032245

Device Name: Arthrex FiberTape™ Family

Indications For Use:

The Arthrex FiberTape™ Family suture products, like it's predecessor the FiberWire™ Family, are intended for use in approximation and/or ligation of soft tissue, including use of allograft tissue for orthopedic surgeries.

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

for Mark N Milhous

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

(ODE) Number K032245