MAY - 1 2000

K00-0506

# 510(k) Summary

02/02/00

**Company:** Arthrex, Inc.
**Address:** 2885 S. Horseshoe Drive, Naples, FL 34104
**Phone:** (941) 643-5553 (ext. 117)
**Fax:** (941) 643-6218
**Contact:** Vernon C. Brown
Manager of Regulatory Affairs

**Trade Name:** Arthrex Bio-Fastak Suture Anchor
**Common Name:** Suture Anchor
**Classification:** Fastener, Fixation, Biodegradable, Soft Tissue

**Description:**
The Bio-Fastak Suture Anchor is manufactured using poly (L, DL-lactide). It is a threaded design with an eyelet of braided polyester suture insert molded down the length of the device. The anchor has a hex head, which is seated in a disposable driver for insertion purposes. Prior to driving in the anchor, it is necessary to prepare the bone using a tap. Once in place, additional suture may be passed through the eyelet and used to reattach soft tissue to the bone.

**Intended Use:**
The Bio-Fastak Suture Anchor is intended for fixation of soft tissue to bone. This product is intended for the following indications:

***Shoulder***: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

***Foot/Ankle***: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair

***Knee***: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

***Hand/Wrist***: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

***Elbow***: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligamant Reconstruction

***Pelvis***: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency

**Substantial Equivalence:**
By definition, substantial equivalence means that a device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and does not raise different questions regarding safety and effectiveness from the predicate device.

The differences between the Bio-Fastak Suture Anchor and the predicate devices cited do not raise any different questions regarding safety and effectiveness. Furthermore, the material is well characterized, and has been used in a predicate device with a similar indication. The device, as designed, is as safe and effective as the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Vernon C. Brown
Manager of Regulatory Affairs
Arthrex Inc.
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K000506
Trade Name: Bio-FASTak Suture Anchor
Regulatory Class: II
Product Codes: MAI, HWC
Dated: February 2, 2000
Received: February 15, 2000

Dear Mr. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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 control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Donna R. Bochner

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

K000506

## Indications for Use

The **Bio-Fastak** is intended for fixation of suture to bone. This product is intended for the following indications:

***Shoulder***: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

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***Pelvis***: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency

Dianne R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000506