3/12/99

510(k) Summary K983843

02/26/99

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

Trade Name: Arthrex Bio-Button
Common Name: Soft Tissue Fastener
Classification: Fastener, Fixation, Biodegradable, Soft Tissue

Description:
The Bio-Button is a PLA disc consisting of four holes for passing suture. Once suture is passed through the soft tissue, the two free ends of the suture are brought through the Bio-Button in any two holes. Soft tissue reattachment is accomplished by tying the suture ends over the Bio-Button securing the suture and disc to the bone.

Intended Use:
The Arthrex Bio-Button is intended for the suture fixation of soft tissue to bone, utilizing the Arthrex® Corkscrew™ Suture Anchor, and polyester braided sutures appropriate to the procedure, up to size 5 (single strand). This product is intended for use in repairing rotator cuff tears.

Similarities and Differences with Marketed Devices:
The Bio-Button has the same diameter and thickness as the discs used with the Corkscrew Parachute (K974847). Furthermore, it is made out of the same material. There are slight variations in design, including removal of the cross and enlarging the diameter of the four holes to accept #5 suture. None of these changes cause the Bio-Button to be any less safe and effective than the predicate device nor do they raise any different questions regarding safety and effectiveness from the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 1999

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

Re: K983843
Trade Name: Bio-Button
Regulatory Class: II
Product Codes: MAI, GAS, and KGS
Dated: January 22, 1999
Received: January 25, 1999

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 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. 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 (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 requirement, 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) 594-4659. 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" (21 CFR 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K98 3843

Indications for Use

The **Arthrex Bio-Button** is intended for the suture fixation of soft tissue to bone, utilizing the Arthrex® Corkscrew™ Suture Anchor and polyester braided sutures appropriate to the procedure, up to size 5 (single strand). This product is intended for use in repairing rotator cuff tears.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983843