

APR 14 1999

510(k) Summary

02/01/99

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

Trade Name: Arthrex Headed Bio-Absorbable Corkscrew
Common Name: Bio-Absorbable Corkscrew Fastener
Classification: Fastener, Fixation, Biodegradable, Soft Tissue

Description:

The Headed Bio-Absorbable Corkscrew is manufactured using poly (L, DL-lactide). It is a threaded design with a rounded head which is slotted to accept the associated driver. Prior to driving in the anchor, it is necessary to prepare the bone using a tap.

Intended Use:

The Headed Bio-Absorbable Corkscrew 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 Ligament Reconstruction

Substantial Equivalence:

Substantial equivalence is substantiated when 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.

A substantial equivalence comparison is given in Table A.

In regards to the material, Poly (L,DL-Lactide), it is currently used in the Synthes Polypin which recently received FDA marketing clearance. This material has undergone extensive in-vitro and in-vivo testing by Synthes.

In addition to the testing performed by Synthes, an independent evaluation of the material was conducted by Claes et. al. ("New bioresorbable pin for the reduction of small bony fragments: design, mechanical properties and in vitro degradation" – Biomaterials, 1996, Vol. 17 No. 16).

None of the aforementioned differences make the Arthrex Headed Bio-Absorbable Corkscrew any less safe and effective than the predicate devices. Furthermore, they do not raise any different questions regarding safety and effectiveness from the predicate devices.

Table A: Substantial Equivalence Comparison

Company	Device	Intended Use	Material	Size(s)	Insertion	Pull-Out
Arthrex	Headed Bio-Absorbable Corkscrew	Soft tissue to bone fixation	Poly (L, DL-lactide)	5.0mm	Screw in	79.3 lbs.*
Arthrex	FASTak	Soft tissue to bone fixation	Titanium Alloy	2.4mm #2 suture	Screw in	55.40 lbs.* As reported: K971723
Zimmer	Bio-Statak (RSTA)	Soft tissue to bone fixation	Poly (L-lactic) acid	5.0mm #2 suture	Screw in	Diaphyseal: 69 lbs.** Metaphyseal: 71 lbs. Cancellous: 70 lbs.
Linvatec	Bio-Anchor	Soft tissue to bone fixation	Poly (L-lactic) acid	3.5mm #0 to #2 suture	Impact	Diaphyseal: 33 lbs.** Metaphyseal: 49 lbs. Cancellous: 29 lbs.
Ethicon	Mitek 3.5mm Panalok Wedge Absorbable Suture Anchor	Soft tissue to bone fixation.	Poly (L(-)-lactide) polymer	3.5mm	In tunnel fixation	Unknown

* Pull-out testing performed using a 20 lb. density foam block to simulate poor quality bone

** "Suture Anchors Product Information Guide" – Orthopedic Special Edition: Winter/Spring 1997



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K990361
Trade Name: Headed Bio-Absorbable Corkscrew
Regulatory Class: II
Product Codes: MAI and HWC
Dated: February 3, 1999
Received: February 5, 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.

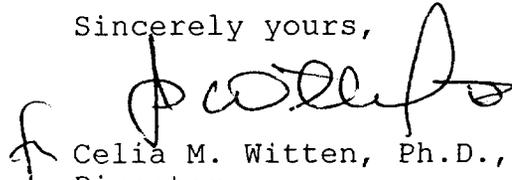
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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 (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

Indications for Use

The **Headed Bio-Absorbable Corkscrew** is intended for fixation of soft tissue to bone. This product is intended for the following indications:

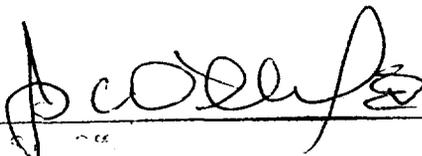
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

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(Division of) Restorative Devices
Division of Restorative Devices
510(k) Number K990361

Prescription Use X
(Per 21 CFR 801.109)