

AUG 6 1998

K974847

510(k) Summary

12/24/97

Company: Arthrex, Inc.
Address: 2885 S. Horseshoe Drive, Naples, FL 34104
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Contact: Scott M. Durlacher
Director of Regulatory Affairs and Quality Assurance (ext. 117)

Trade Name: Arthrex Parachute Corkscrew Suture Anchor
Common Name: Suture Anchor
Classification: Fastener, Fixation, Nondegradable, Soft Tissue (per 21 CFR 888.3030)
Fastener, Fixation, Biodegradable, Soft Tissue

Description:

The Parachute Corkscrew Suture Anchor is a 2 component product consisting of a titanium alloy anchor with a PLA disc attached by a #4 non-absorbable braided polyester suture. Once the tissue is in the desired position, the Parachute Corkscrew is inserted through the tissue and into bone. The insertion is discontinued when the soft tissue/bone apposition has been achieved. The distance between the disk and anchor ensures that the head of the anchor is not protruding from the surface of the bone.

The anchor is made of Titanium 6Al-4V alloy (ASTM F136-96), the biocompatibility of which has been well documented. In regards to the material for the disc, Poly (L-lactide), it is currently being used in the Arthrex Bio-Interference Screw, which has received clearance for both bone and soft tissue fixation.

Intended Use:

The Parachute Corkscrew Suture Anchor is intended for fixation of 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

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

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.

A substantial equivalence comparison is given in Table A. Although there are slight differences in design and failure strength between the various anchors, the critical value for the FASTak and Bio-Anchor is the tensile strength of the suture. Since the failure strength of the Parachute Corkscrew is greater than the knot tensile strength of size 2 suture (i.e. the maximum recommended size of suture for both the FASTak and the Bio-Anchor), none of the aforementioned differences make it 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

Company	Device	Intended Use	Material
Arthrex	Parachute Corkscrew	Soft tissue to bone fixation	Anchor: titanium a Disc: Poly (L-lacti
Arthrex	FASTak	Soft tissue to bone fixation	Titanium Alloy
Linvatec	Bio-Anchor	Soft tissue to bone fixation	Poly (L-lactic) aci

* Testing performed using a 20 lb. density foam block to simulat

** "Suture Anchors Product Information Guide" – Orthopedic S

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Equivalence Comparison

	Size(s)	Insertion	Failure Strength
Alloy (disc)	3.5mm w/8mm PLA disc	Screw in	40.98 lbs.*
	5.0mm w/8mm PLA disc		
	2.4mm w/#2 suture	Screw in	55.40 lbs.*
Alloy	3.5mm w/#0 to #2 suture	Impact	Diaphyseal: 33 lbs.** Metaphyseal: 49 lbs. Cancellous: 29 lbs.

in poor quality bone

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Scott M. Durlacher
•Director of Regulatory Affairs and Quality Assurance
Arthrex, Inc.
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K974847
Trade Name: Arthrex Parachute Corkscrew Suture Anchor
Regulatory Class: II
Product Codes: MBI and GAT
Dated: May 21, 1998
Received: June 2, 1998

Dear Mr. Durlacher:

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.

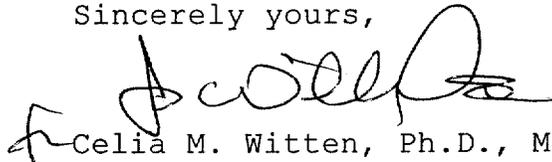
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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

