MAR - 9 2001

510(k) Summary

510(k) Number: K003816
Contact Person: Vernon C. Brown, Manager of Regulatory Affairs
Date Prepared: November 22, 2000

Trade/Proprietary Name: Titanium Fixation System
Classification Name: Fastener, fixation, non-degradable, soft tissue
Predicate Devices: ANCHORLOK™ Soft Tissue Anchor System Wright Medical, Mitek Knotless Anchor Mitek Surgical Products, Straight-In Orthopedic fixation system, Influence, Inc., KSEA Flipptack Karl Storz Endoscopy-America, and Acumed Suture Anchor by Acumed, Inc.

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 Titanium Fixation Device is intended for arthroscopic and limited mini-open surgeries requiring soft tissue fixation to bone for repair of shoulder, hand/wrist, foot/ankle, knee, elbow, and pelvis.

Description:

The Arthrex, Inc. Titanium Fixation Device is a manually operated surgical device intended for suture fixation in the repair of tendons and ligaments. The implant is constructed of titanium and the suture is composed of #2 braided polyester. These components are used in a wide variety of medical devices and prior approved implants of this type.

Substantial Equivalence:

The Arthrex, Inc. Titanium Fixation Device is substantially equivalent to predicate devices where the basic features and intended uses are the same. Minor differences between the Titanium Fixation Device 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

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

Re: K003816
Trade Name: Arthrex Titanium Corkscrew, 3.5mm, 5.0mm, 6.5mm
Regulatory Class: II
Product Code: HWC and MBI
Dated: December 8, 2000
Received: December 11, 2000

Dear Mr. Vernon:

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,

for Mark N Melkerson

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

Indications for Use

The Titanium Corkscrew is intended for fixation of suture to bone. This product is intended for the following indications:

Shoulder: Rotator Cuff Repairs, 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, and 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

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

for Mark N Melkerson

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

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