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VIII. 510(k) Summary of Safety and Effectiveness

Arthrex V-Tak™

Manufacturer / Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, Florida 34108-1945
510(k) Contact:	Ann Waterhouse, RAC Sr. Regulatory Affairs Specialist Telephone: (239) 643-5553 ext. 1179 FAX: (239) 598-5508
Trade Name:	Arthrex V-Tak™
Common Name:	Fastener, Fixation, Degradable, Soft Tissue
Product Code / Classification Name:	MAI, 21 CFR 888.3030 Fastener, Fixation, degradable, Soft Tissue
Predicate Device:	Arthrex WristTak K022234

Device Description and Intended Use:
The Arthrex V-Tak™ is a fully threaded, notched, degradable anchor.

The Arthrex V-Tak™ is intended to provide fixation of suture to bone in surgeries of the foot, ankle, hand, wrist, and elbow.

Substantial Equivalence:
The Arthrex V-Tak™ is substantially equivalent to the predicate Arthrex WristTak in which the basic features and intended uses are the same. Any differences between the Arthrex V-Tak™ and the predicate Arthrex WristTak are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the V-Tak™ is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 1 2005

Ms. Ann Waterhouse, RAC
Regulatory Affairs Specialist
Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K050634
Trade/Device Name: Arthrex V-Tak™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 10, 2005
Received: March 11, 2005

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 Division
D.O.

f/t:Psung:tmj:3-18-05

III. Indications for Use Form

510(k) Number (if known): K050634

Device Name: Arthrex V-Tak™

Indications for Use:

The Arthrex V-Tak™ is intended to provide fixation of suture to bone in surgeries of the foot, ankle, hand, wrist, and elbow. Specific indications are listed below:

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

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

Foot: Hallux Valgus reconstruction

Ankle: Mid-foot reconstruction

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K050634