

JAN 28 2000

510(k) Summary

1/28/1999

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

Trade Name: Arthrex TissueTak
Common Name: NA
Classification: Fastener, Fixation, Biodegradable, Soft Tissue

Description:

The Arthrex TissueTak is manufactured using Poly (L, DL-lactide). It is cannulated with an oblong head and seven raised ridges along the circumference of the central shaft. There are two spikes on the head of the device to aid in soft tissue fixation.

Intended Use:

The TissueTak is intended for fixation of soft tissue to bone for reattachment of the glenoid labrum or inferior glenohumeral ligament in patients with primary or recurrent anterior dislocation or subluxation of the shoulder in association with adequate post operative immobilization

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.

The material for the TissueTak, Poly (L,DL-Lactide), is currently used in the Synthes Polypin, which has received FDA marketing clearance and has undergone extensive in-vitro and in-vivo testing. Further 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).

The Arthrex TissueTak has the same intended use as the as the Acufex Suretac and the Bionx Bankart Tack, and the technological differences between these products do not raise different concerns regarding the safety and efficacy of the Arthrex TissueTak.



JAN 28 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Vernon C. Brown
Manager of Regulatory Affairs and
Quality Assurance
Arthrex, Incorporated
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K990340
Trade Name: TissueTak™
Regulatory Class: II
Product Code: MAI and HWC
Dated: October 29, 1999
Received: November 1, 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.

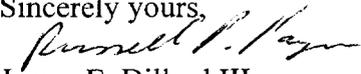
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

Page 2 – Mr. Vernon C. Brown

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,



James E. Dillard III

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Indications for Use

The TissueTak™ is intended for fixation of soft tissue to bone for reattachment of the glenoid labrum or inferior glenohumeral ligament in patients with primary or recurrent anterior dislocation or subluxation of the shoulder in association with adequate post operative immobilization

Russell J. Payne

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number R990340

Prescription Use X
(Per 21 CFR 801.109)