

MAR - 5 1998

K974291

510(k) SUMMARY FOR K9XXXXX

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SUBMITTER

NAME Mitek Surgical Products, Inc.
ADDRESS 60 Glacier Drive, Westwood, MA 02090
TEL# 781-251-2700
CONTACT Robert Zoletti, Manager, Regulatory Affairs
DATE November 14, 1997

NAME OF DEVICE

CLASSIFICATION NAME Staple, Fixation, Bone, & soft tissue
COMMON NAME A device for holding tissue in
apposition
PROPRIETARY NAME Mitek BTB Absorbable(PLA) Cross Pin

PREDICATE DEVICE

Linvatec PLA Bioscrew

DESCRIPTION OF DEVICE

FUNCTION

To hold bone graft in position during healing period

DEVICE DESIGN

The Cross Pin is 1.654" long by 0.105" dia with a
conical tip by .180 long.

MATERIALS USED

The Cross Pin is molded from Purac(PLA)

INTENDED USE

To hold a bone tendon bone graft in place by cross pinning
in the femoral tunnel during a period of time following
surgery allowing the natural healing process(es) to occur.

COMPARISON TO PREDICATE DEVICE

The Cross Pin compares to the predicate device,
Linvatec Bioscrew, (K)960940, in that it is made from
the same type of material (PLA), and is used to hold
the bone graft in place in the femoral tunnel during
the rehabilitation and healing process. The
preparation for the ACL reconstruction surgery is
similar for each device, i.e., tibial and femoral bone
tunneling and graft placement into the tunnel. The
fixation process of the Bioscrew wedges the bone plug
in place while the Cross Pin secures the bone plug by
pinning(2 pins) across the plug into the adjacent
femur.

DESCRIPTION OF NON CLINICAL TESTS

Bench top Bending and Shear tests were done on the PLA pins and strength comparisons to the Bioscrew in pull out tests were done to the Bioscrew. The results showed that there was no significant strength difference between the two. Eight week In-vitro tests were also done and found to have results that were comparable to "zero" day results.

DESCRIPTION OF CLINICAL TESTS

No clinical tests were done for this product

CONCLUSIONS FROM TESTS

The bench test performance, molding materials, and intended use show that the two devices perform equally.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1998

Mr. Edward F. Kent
Vice President
Regulatory Affairs
Mitek® Products
60 Glacier Drive
Westwood, Massachusetts 02090

Re: K974291
Trade Name: BTB Absorbable (PLA) Cross Pin
Regulatory Class: II
Product Codes: HTY and MAI
Dated: February 25, 1998
Received: February 27, 1998

Dear Mr. Kent:

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.

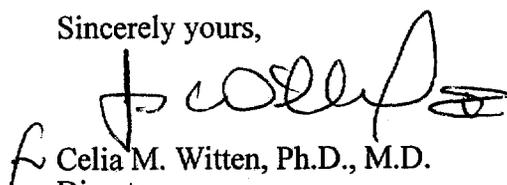
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Edward F. Kent

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,

A handwritten signature in black ink, appearing to read "C. Witten", with a horizontal line extending to the right.

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

510(k) Number (if known): _____

Device Name: MITEK 2.7mm BTB CROSS PIN

Indications For Use: Femoral fixation of autograft or allograft
ACL Bone Tendon Bone Grafts

(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 Devices
510(k) Number 16974291

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)