K974341

APR 16 1998

Mitek® PRODUCTS

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a Johnson & Johnson company

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SUBMITTER

NAME	Mitek Products
ADDRESS	60 Glacier Drive, Westwood, MA 02090
Tel No.	781-251-2700
CONTACT	Robert Zoletti, Manager, Regulatory Affairs
DATE	October 20, 1997

NAME OF DEVICE

CLASSIFICATION NAME	Staple, fixation, bone and soft tissue
COMMON NAME	A device for holding soft tissue in apposition
PROPRIETARY NAME	Mitek 3.3mm ST Cross Pin

PREDICATE DEVICE

Acufex EndoButton (K) 933948

DESCRIPTIION OF DEVICE

FUNCTION

Hold a Semi Tendonosus soft tissue graft in position during healing in the femoral bone tunnel.

DEVICE DESIGN

The Cross Pin is 1.654 " long by 0.132" dia. with a conical tip by 0.180" long.

MATERIALS USED

The Cross Pin is molded from Purac PLA

INTENDED USE

To hold a Semi Tendonosus ST (soft tissue) graft in place in the femoral tunnel during the healing period following ACL reconstrution surgery.

COMPARISON TO PREDICATE DEVICE

The PLA 3.3mm ST Cross Pin compares to the Acufex EndoButton in that the indication for use is the same and the function of the device(s) are similar. They hold a soft tissue graft in position in the femoral tunnel during the healing process after ACL reconstructive surgery. The Cross Pin holds the device by having passed through the graft within the bone tunnel, facilitated by use of the Mitek ACL guide system, and into the opposite bone tunnel wall of the femur. The EndoButton holds the soft tissue graft in place with suture/tape which is then anchored over the EndoButton which is placed onto the anterior lateral femoral cortex.

DESCRIPTION OF NON CLINICAL TESTS

Bench fixation strength tests, bending and shear, were done comparing the Acufex EndoButton and the Mitek 3.3mm ST Cross Pins. These tests showed statistical equivalence between the two devices, in both strength and in stiffness. Also, In-Vitro evaluation tests were conducted to show the effect of cross pin orientation on the ultimate strength of the hamstring grafts in ACL reconstruction.

DESCRIPTION OF CLINICAL TESTS

No clinical tests were done.

CONCLUSIONS FROM TESTS

The bench test data and the overall graft delivery and bone tunnel preparation work show that the devices are applied in a similar manner and perform equally.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 1998

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

Re: K974341
Trade Name: 3.3mm ST 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.

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 Stephen Rhodes

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): K974341

Device Name: Mitek 3.3mm (ST) Cross Pin

Indications For Use:

Femoral fixation of autograft or allograft
ACL soft tissue 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 K974341
510(k) Number

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)