

K982400

AUG 24 1998

Mitek[®]
PRODUCTS

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ETHICON, INC.
a Johnson & Johnson company

510(k) SUMMARY FOR K982440

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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 August 13, 1998

NAME OF DEVICE

CLASSIFICATION NAME Staple, Fixation, Bone
COMMON NAME Appliance for reconstruction of
bone to soft tissue
PROPRIETARY NAME Mitek Micro Anchor

PREDICATE DEVICE

Suture

DESCRIPTION OF DEVICE

FUNCTION

Fixation of USP #3/0 suture below bone surface.

DEVICE DESIGN

The Mitek Micro Anchor is 3.7mm in length by 1.3mm in diameter. It is manufactured from Titanium 6Al 4V and uses a Nitinol arc. It is similar in design to the Mitek GII Mini Anchor. The same methods of manufacturing and assembly are used for the Micro Anchor as those used for manufacturing all other Mitek metal anchors. The Mitek Mini anchor design was first cleared to market by US FDA in K915089 and K930892.

MATERIALS USED

The Mitek Micro Anchor delivery system consists of a Mitek Micro Anchor, a drill bit, and an Insertor.

INTENDED USE

The device is used to anchor suture into bone. The suture is subsequently used by the surgeon to reattach the repositioned/injured soft tissue to bone. The purpose of this 510(k) submission is to obtain clearance for the Mitek Micro Anchor for the lateral canthoplasty repair/reconstruction of collateral ligaments, flexor and extension tendons at the PIP (Proximal Interphalangeal) DIP (Distal Interphalangeal), and MCP (Metacarpal Interphalangeal) joints for all digits. The intended use is the same as the predicate device, i.e., suture, when used to approximate soft tissue to bone during a period of rehabilitation.

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COMPARISON TO PREDICATE DEVICE

It has greater strength than USP #3/0 suture, and is the same "design" as the Mitek Mini Anchor.

DESCRIPTION OF NON CLINICAL TESTS

The Mitek Micro Anchor pull tests from cadaveric and porcine locations produced an average failure load (LBS) of:

| | |
|---------------------------|---------------|
| 1) CADAVER HAND | 9.67, SD 1.32 |
| 2) CADAVER SKULL | 7.97, SD 1.92 |
| 3) PIG METACARPALS | 7.28, SD 0.72 |
| 4) SUTURE W/ BONE TUNNELS | 5.73, SD 0.46 |

USP Class I knot pull synthetic sterilized #3/0 suture, double strand, single knot, is 4.22 lb.

Suture tissue failure for tendinous tissue is 15.75 lb., and capsular tissue is 21.80 lb.. Reference: Soft Tissue Fixation to Bone, Daniel B. Robertson, MD et al, The American Journal of Sports Medicine, Vol. 14, No. 5, 1986.

DESCRIPTION OF CLINICAL TESTS

The clinical tests were done in accordance with IDE #G880026. Safety and effectiveness was based upon the results obtained in the clinical trials and their equivalence to historical data for the identical surgical procedure.

CONCLUSIONS FROM TESTS

The device met the design criteria.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 24 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Edward F. Kent
Mitek Products
60 Glacier Drive
Westwood, Massachusetts 02090

Re: K982420
Trade Name: Mitek Micro Anchor
Regulatory Class: II
Product Codes: JDR and HWC
Dated: June 12, 1998
Received: June 15, 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.

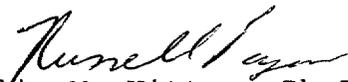
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Edward F. Kent

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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


for 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): K982420

Device Name: MIBEK MICRO ANCHOR

Indications For Use:

REPAIR/RECONSTRUCTION OF COLLATERAL LIGAMENTS, FLEXOR AND EXTENSION TENDONS AT THE PIP (PROXIMAL INTERPHALANGEAL), DIP (DISTAL INTERPHALANGEAL), AND MCP (METACARPAL INTERPHALANGEAL) JOINTS FOR ALL DIGITS

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982420

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)