

Mitek
PRODUCTS

FEB 13 1998

ETHICON.INC.
a Johnson-Johnson company

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510(k) SUMMARY FOR ~~K9XXXXX~~ K974345

Page 1 of 2

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 19, 1997

NAME OF DEVICE

CLASSIFICATION NAME Staple, fixation, bone & soft tissue
COMMON NAME Device for holding soft tissue in
apposition
PROPRIETARY NAME Mitek Knotless Anchor

PREDICATE DEVICE

Mitek GII

DESCRIPTION OF DEVICE

FUNCTION

Hold soft tissue in apposition during healing process

DEVICE DESIGN

The device is 0.430" lg by 0.109" wide with with two
0.026" by 85 degree arcs.

MATERIALS USED

Titanium body and Nitinol arcs

INTENDED USE

To lock into bone and hold suture and tissue in apposition
during the healing process

COMPARISON TO PREDICATE DEVICE

Identical intended use with variance in suture
handling and knotless function. Made from identical
materials. Patient preparation is same with the
exception of the tissue apposition process, i.e., the
knotless anchor uses a looped version of suture to
hold the tissue in place and the GII uses knots to
perform the tissue apposition.

DESCRIPTION OF NON CLINICAL TESTS

Bench top tests showed statistically equivalent
strength between the knotless and GII anchors. The
pull out failure force from pig femora for : Mitek
GII Anchor was 55.63lbs, SD 17.12, and for Knotless
Anchor was 60.96lbs, SD 14.29.

003006

DESCRIPTION OF CLINICAL TESTS

Clinical tests for the Mitek anchors were done in accordance with IDE G880026.

CONCLUSIONS FROM TESTS

The Mitek Anchor was found safe and effective by FDA in K892126.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K974345
Trade Name: Mitek Knotless Anchor
Regulatory Class: II
Product Code: MBI
Dated: November 19, 1997
Received: November 19, 1997

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.

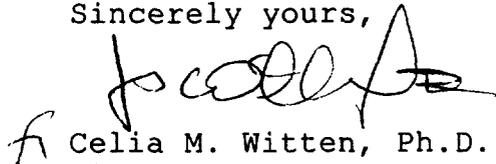
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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



f 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): K974345

Device Name: Mitek Knotless Anchor

Indications For Use:

Shoulder: Bankart repair, SLAP Lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsulo-labral reconstruction, biceps tenodesis, deltoid repair.

Ankle: Lateral instability, medial instability, Achilles tendon repair/reconstruction, midfoot reconstruction.

Foot: Hallux Valgus reconstruction.

Elbow: Tennis Elbow repair, biceps tendon reattachment.

Knee: Extra capsular repairs, Reattachment of: medial collateral ligament, lateral collateral ligament, posterior oblique ligament, or joint capsule to tibia and joint capsule closure to anterior proximal tibia, extra capsular reconstruction, ITB tenodesis, patellar ligament and tendon avulsions

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K974345