

NOV 10 1997

SUMMARY OF SAFETY AND EFFECTIVENESS
MITEK POLYPROPYLENE "H" DEVICE

CONTACT

Edward F. Kent Vice President
Regulatory Affairs & Quality Assurance
August 11, 1997

DATE

NAME OF DEVICE

CLASSIFICATION NAME
COMMON NAME
PROPRIETARY NAME

MITEK POLYPROPYLENE "H" DEVICE

PREDICATE DEVICE

ACUFEX "T" FIX DEVICE
NON ABSORBABLE SUTURE

DESCRIPTION OF DEVICE
FUNCTION

To hold (meniscal) soft tissue in apposition during the healing time period.

DEVICE DESIGN

The "H" Fix is cylindrical in cross section and configured to have one leg of the letter "H" in a 90 degree opposed position to the other.

MATERIALS USED

The Mitek non absorbable "H" Fix is made from polypropylene.

INTENDED USE

The device is surgically placed across (through) a tear in the meniscal tissue of the knee with a needle applicator and released. The released "H" Fix produces a holding (compressive) force across the tear causing tissue apposition, which allows the natural healing process (at the tear) to occur.

COMPARISON TO PREDICATE DEVICE(S)

The Mitek polypropylene "H" Fix device is similar to the Acufex T-Fix device in function and material, non absorbable biocompatible polymers. The T-Fix is surgically placed through a tear in the knee meniscus, toggled and then tied with sutures over external tissues to hold the "T" in place. The "H" Fix is placed through the tear in a cannulated needle and extended into the tissue, the spring forces in the material are induced by proper placement in the tissue and by the device length.

DESCRIPTION OF NON CLINICAL TESTS

The Mitek polypropylene non absorbable "H" Fix pull tests from bovine meniscus provided an average failure load of 16.29 pounds. The Mitek "H" device showed a significantly greater failure force than the predicate Acufex "T" Fix device when tested in the bovine meniscus.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1997

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

Re: K973009
Trade Name: Mitek Non Absorbable "H" Fix
Regulatory Class: II
Product Codes: MBI and HRX
Dated: August 12, 1997
Received: August 13, 1997

Dear Mr. Kent:

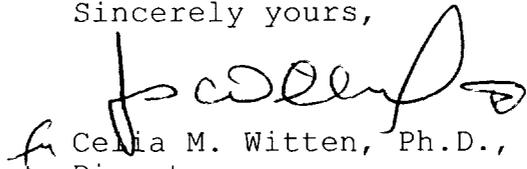
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


Cecilia 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 "H" Fix

Indications For Use: Mitek meniscal fasteners ("H" Fix) are intended for the repair of torn meniscal tissue as well as the repair of a separation of the meniscus from the synovium.

(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 K973009

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)