

SUMMARY OF SAFETY AND EFFECTIVENESS
MITEK ABSORBABLE "H" DEVICE

K970119

SUBMITTER

NAME	Mitek Products
ADDRESS	60 Glacier Drive, Westwood, MA 02090
TEL #	617-461-9700
CONTACT	Edward F. Kent Vice President Regulatory Affairs
DATE	January 10, 1997

NAME OF DEVICE

CLASSIFICATION NAME	
COMMON NAME	
PROPRIETARY NAME	MITEK ABSORBABLE "H" DEVICE

PREDICATE DEVICE

ACUFEX "T" FLX DEVICE
PDS II SUTURE

DESCRIPTION OF DEVICE

FUNCTION

To hold outer 1/3 (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 absorbable "H" Fix is made from PDS (polydioxanone) polymer.

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. The tear in the meniscus for repair with the "H" PDS device should be located in the outer 1/3 zone of the meniscus, i.e., red/red zone.

COMPARISON TO PREDICATE DEVICE(S)

The Mitek absorbable "H" Fix device is similar to the Acufex T-Fix device in function. 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-Fix 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 device length.

DESCRIPTION OF NON CLINICAL TESTS

The Mitek absorbable "H" Fix pull tests from cadaver meniscus provided an average failure load of 12.06 pounds.

MITEK MENISCAL FASTENER

Catalog No. XXXXXX

Catalog No. YYYYYY

DESCRIPTION

Mitek Meniscal Fasteners are molded polymeric implants used to repair tears in the meniscus. Fasteners provide the means for firmly securing together the edges of a tear in the meniscus or across the synovial meniscal junction. The fasteners are available in absorbable PDS (polydioxanone).

Studies of the polydioxanone polymer have found it to be nonantigenic, nonpyrogenic, and it elicits only a slight tissue response during healing.

Mitek instruments - Applicator, probe and rasp used to assist in the procedure of measuring, preparing and inserting the Mitek Meniscal Fastener.

ACTIONS

PDS (Polydioxanone)

The absorption characteristics of polydioxanone have been extensively studied. The general mechanism by which in vivo degradation of polydioxanone occurs is hydrolysis. The in vivo hydrolysis of polydioxanone cleaves the ester linkages and initially results in the loss of tensile strength. Ultimately the hydrolyzed polymer is eliminated from the body, primarily in urine.

Studies conducted on devices made from polydioxanone polymer indicate minimal absorption until about the 90th post-implantation day.

The results of implantation studies of polydioxanone molded articles in animals indicate that approximately 85% of its original strength remains 5 weeks after implantation. At 7 weeks post implantation approximately 12% of its original strength is retained.

CONTENTS

A Meniscal Fastener secured in a delivery needle is supplied sterile. Contents are sterile unless the package is damaged or opened. Do not re-sterilize PDS (polydioxanone).

INDICATIONS

Mitek Meniscal Fasteners are intended for the repair of torn meniscal tissue in the red/red zone of the meniscus (outer 1/3) as well as the repair of a separation of the meniscus from the synovium.

CONTRAINDICATIONS

These fasteners (being absorbable) are not to be used where prolonged (beyond 6 weeks) approximation of tissue under stress is required.

PRECAUTIONS

1. Care should be taken to avoid damage when handling the fasteners. Avoid the crushing or crimping of the fasteners by the application of needle holders or forceps.
2. A surgeon should not attempt clinical use of the Mitek Meniscal Fasteners before reviewing instructions for use and rehearsing the installation procedure.
3. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks.
4. Discard used needles in sharps containers.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 1998

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

Re: K970119
Mitek Absorbable Polydioxanone "H" Device
Regulatory Class: II
Product Code: MBI
Dated: January 8, 1998
Received: January 9, 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.

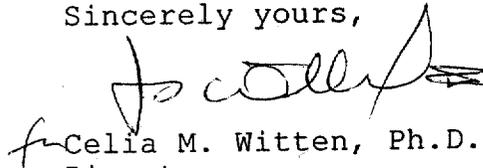
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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


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): K970119

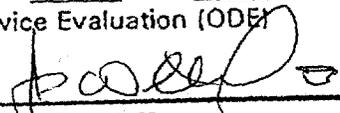
Device Name: Mitek "H" Fix PDS device

Indications For Use:

Mitek meniscal fasteners "H" Fix PDS
are intended for use in the repair or torn
meniscal tissue in the red/red zone of the
meniscus (outer 1/3) 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 K970119

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)