K983818

NOV 23 1998

mitek® PRODUCTS

60 GLACIER DRIVE • WESTWOOD • MA • 02090
PHONE (781) 251-2700 • TOLL-FREE (800) 356-4835 • FAX (781) 461-9166

ETHICON, INC.
a Johnson & Johnson company

510(k) SUMMARY FOR MITEK FASTIN[R] RC ANCHOR

SUBMITTER

NAME	Mitek Products
ADDRESS	60 Glacier Drive Westwood, MA 02090
TEL	781-251-2700
CONTACT	Robert Zoletti, Manager, Regulatory Affairs
DATE	October 2, 1998

NAME OF DEVICE

CLASSIFICATION NAME	Staple, Fixation, bone
COMMON NAME	Appliance for reconstruction of bone to soft tissue
PROPRIETARY NAME	Mitek FASTIN[R] RC Anchor

PREDICATE DEVICE Mitek FASTIN[R] Anchor

DESCRIPTION OF DEVICE The Mitek FASTIN[R] RC threaded titanium alloy suture anchor is preloaded on a disposable inserter assembly intended for fixation of two strands of #2 suture to bone. The Mitek FASTIN[R] RC Anchor is designed to be used in the surgical repair of the rotator cuff.

INTENDED USE

The threaded Anchor holds sutures in bone for the period of time required to allow for patient rehabilitation and tissue healing.

COMPARISON TO PREDICATE DEVICE

The Mitek FASTIN[R] RC is the same design as the predicate device, Mitek FASTIN[R].

DESCRIPTION OF NON CLINICAL TESTS

Based upon mechanical tests done and contained in the literature, it can be stated that the holding power of the Mitek FASTIN[R] RC Anchor is equal to or greater than the Mitek FASTIN[R].

ASSESSMENT OF PERFORMANCE DATA

The Mitek FASTIN[R] RC is the same device as the Mitek FASTIN[R] which was legally cleared for marketing in March 95.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 1998

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

Re: K983818
Trade Name: Mitek Fastin RC Anchor
Regulatory Class: II
Product Codes: MBI, HWC, GAM, and GAS
Dated: October 27, 1998
Received: October 29, 1998

Dear Mr. Kent:

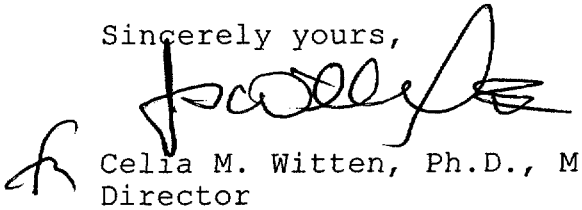
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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): K983818

Device Name: Mitek FASTIN[R] RC Anchor

Indications For Use: Rotator cuff repair

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

Concurrence of CDRH , Office of Device Evaluation (ODE)

Prescription Use X OR Over –The-Counter Use____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983818