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ATTACHMENT H

SUMMARY OF SAFETY & EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Mitek Products is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Mitek Products choose to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the proposed RigidFix™ Tibial Soft Tissue ACL Crosspin System is as follows:

Trade Name:	RigidFix™ Tibial Soft Tissue ACL Crosspin System
Sponsor:	Mitek Products 249 Vanderbilt Avenue Norwood, MA 02062 Registration: 1221934
Device Generic Name:	Appliance for reconstruction of bone to soft tissue
Classification:	According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.
Predicate Devices:	Mitek – 3.3mm ST Femoral RigidFix™ Crosspin System Linvatec BioScrew® Absorbable Interference Screw

All of the devices mentioned above have been determined substantially equivalent by FDA.

Device Description: The device described in this 510(k) is a sterile, disposable device designed for single patient use only. The crosspins are constructed of bioabsorbable Poly L-lactic Acid (PLA).

Indications for Use: The RigidFix™ Tibial Soft Tissue ACL Crosspin System is indicated for tibial fixation of autograft or allograft ACL soft tissue grafts.

Safety and Performance: Functional and integrity bench testing and Biocompatibility testing (according to the FDA guidance document, ODE Blue Book Memoradum #G95-1, 1995, Use of International Standard ISO-10933, "*Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*" were performed, and the data supported the substantial equivalence of the 3.3mm ST Tibial RigidFix CrossPin System. Specifically, testing was performed to determine the initial fixation strength of the Tibial RigidFix CrossPin System when used for Hamstring Grafted ACL Reconstructions

Conclusion: Based on the Indications for Use, technological characteristics and safety and performance testing, the RigidFix™ Tibial Soft Tissue ACL Crosspin System has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Mary P. LeGraw
Manager, Regulatory Affairs
Mitek Products
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K010633
Trade/Device Name: RigidFix Tibial ACL CrossPin System
Regulation Number: 888.3040
Regulatory Class: II
Product Code: HWC and MAI
Dated: March 2, 2001
Received: March 2, 2001

Dear Ms. LeGraw:

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 legally marketed predicate 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 requirements, 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if known): Unknown K010633

Device Name: RigidFix™ Tibial ACL CrossPin System

Indications for Use:

The RigidFix™ Tibial ACL CrossPin System is indicated for tibial fixation of autograft or allograft ACL soft tissue grafts (semitendinosus and gracilis).

(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
and Neurological Devices

510(k) Number K010633