

**510(k) Summary
(page 1 of 2)**

Submitter's Name and Address: Mitek Worldwide
249 Vanderbilt Avenue
Norwood, MA 02062
Registration #1221934

Contact Person: Petra Smit, RAC,
Sr. Project Manager Regulatory Affairs

Phone Number: 781-251-3196
Telefax Number: 781-278-9578

Date Summary Prepared: October 8, 2002

Device Trade Name: Mitek RAPIDLOC-PDS Meniscal Repair System

Common name: Biodegradable Fixation Fastener

Classification Name: Fastener, Fixation, Biodegradable Soft Tissue
(Class II, 21 CFR 888.3030, Product code: 87 MAI)

Predicate Device(s): RAPIDLOC Meniscal Repair System
(K002406)
Mitek "H"-Fix Meniscal Fastener (K970119)

Device Description: The RAPIDLOC-PDS Meniscal Repair System consists of a two piece (polydioxanone tophat and polylactic acid backstop) bioabsorbable meniscal tissue fixation implant mounted on a 2/0 pre-knotted PANACRYL braided long-term absorbable suture. It is applied using a cannulated needle and arthroscopic pusher.

Intended Use: The RAPIDLOC-PDS Meniscal Repair System is intended for use in the arthroscopic fixation of longitudinal vertical meniscus lesions (bucket-handle lesions) located in the vascularized area of the meniscus (red-red and red-white areas).

**510(k) Summary
(page 2 of 2)**

Technological Characteristics:

The proposed device has similar technological characteristics and is similar in design and configuration compared to the predicate devices.

Summary of Non-clinical Test:

Testing conducted to characterize performance of the RAPIDLOC-PDS Meniscal Repair System has demonstrated that it is substantially equivalent to the predicate devices and is suitable for the intended use specified.

Clinical Data:

Not Applicable

Conclusion:

Based on 1) safety and performance data, and 2) similarities in design, operating principles, biocompatibility and sterilization method, the Mitek **RAPIDLOC-PDS Meniscal Repair System** has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2002

Ms. Petra C. Smit
Sr. Project Manager, Regulatory Affairs
Mitek Worldwide
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K023388

Trade/Device Name: Mitek RAPIDLOC-PDS Meniscal Repair System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and
Accessories

Regulatory Class: Class II

Product Code: JDR

Dated: December 5, 2002

Received: December 6, 2002

Dear Ms. Smit:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Petra Smit

This letter will allow you to begin marketing your device as described in your Section 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), 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,


for Celia M. Witten, Ph.D., M.D.

Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023388

Device Name: RAPIDLOC-PDS Meniscal Repair System

Indications for Use:

The **RAPIDLOC-PDS Meniscal Repair System** is intended for use in the arthroscopic fixation of longitudinal vertical meniscus lesions (bucket-handle lesions) located in the vascularized area of the meniscus (red-red and red-white areas).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Mellem

(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K023388

Prescription Use yes
(Per 21 CFR 801.109)

OR

Over-the-Counter Use No