510(k) Summary K024115
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MAR 1 3 2003

Submitter's Name and Address:

Mitek Worldwide
249 Vanderbilt Avenue
Norwood, MA 02062
Registration #1221934

Contact Person:

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Date Summary Prepared:

December 2, 2002

Device Trade Name:

MICROFIX QUICKANCHOR Plus

Common name:
Classification Name:

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

Predicate Device(s):

MICRO Anchor, ReSolve QuickAnchor and BIOFASTIN RC suture anchors

Device Description:

The **MICROFIX QUICKANCHOR Plus** is a bioabsorbable polymer implant designed for reattachment of soft tissue to bone. Similar to the currently marketed MICRO Anchor, the implant is mounted on a disposable inserter assembly and placement of the implant is facilitated via use of a sterile, disposable drill bit. There have been no modifications to the drill bit for use with the **MICROFIX QUICKANCHOR Plus** device.

Intended Use: The **MICROFIX QUICKANCHOR Plus** is intended for fixation of soft tissue to bone for the indications listed below:
Hand: Repair/reconstruction of collateral ligaments, flexor and extensor tendon at the PIP (proximal interphalangeal), DIP (distal interphalangeal) and MCP (metacarpal interphalangeal) joints for all digits
Skull: Soft tissue attachment to the parietal, temporal ridge, frontal, mandible, maxilla, zygoma, and perioorbital bones of the skull.

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Technological Characteristics:	The proposed device has similar technological characteristics and is similar in design and configuration compared with the predicate devices.
Summary of Non-clinical Test:	Testing conducted to characterize performance of the **MICROFIX QUICKANCHOR Plus** 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 **MICROFIX QUICKANCHOR Plus** 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

MAR 1 3 2003

Ms. Ruth C. Forstadt
Senior Regulatory Affairs Associate
Mitek Worldwide
249 Vanderbilt Avenue
Norwood, MA 02062

Re: K024115
Trade/Device Name: Mitek Microfix Quickanchor Plus
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: December 12, 2002
Received: December 13, 2002

Dear Ms. Forstadt:

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.

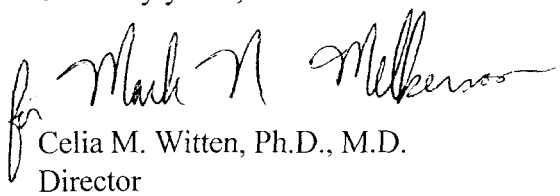
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. 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,



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): K024115

Device Name: **MICROFIX QUICKANCHOR Plus**

The **MICROFIX QUICKANCHOR Plus** is intended for fixation of soft tissue to bone, using suture, for the indications listed below:

Hand: Repair/reconstruction of collateral ligaments, flexor and extensor tendon at the PIP (proximal interphalangeal), DIP (distal interphalangeal) and MCP (metacarpal interphalangeal) joints for all digits.

Skull: Soft tissue attachment to the parietal, temporal ridge, frontal, mandible, maxilla, zygoma, and periorbital bones of the skull.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-the -Counter Use ___

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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