K030995 page 1 of 2

JUN 2 6 2003

SECTION 2 – 510(k) SUMMARY

MINILOK QuickAnchor Plus

Submitter's Name and Address:

Mitek Worldwide
a division of ETHICON Inc.
a Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, MA 02062

Contact Person

Ruth C. Forstadt
Senior Regulatory Affairs Associate
Mitek Worldwide
a division of ETHICON Inc.
a Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, MA 02062
Telephone: 781-251-3188
Facsimile: 781-278-9578
e-mail: rcforstad@ethus.jnj.com

Name of Medical Device

Classification Name:	Fastener, Fixation, Biodegradable, Soft Tissue
Common/Usual Name:	Bone Anchor
Proprietary Name:	MINILOK QuickAnchor Plus

Substantial Equivalence

MINILOK QuickAnchor Plus is substantially equivalent to:

Mini QuickAnchor Plus (K930892, K992487 and K992623) and MicroFix QuickAnchor Plus (K0224115) manufactured by Mitek Worldwide, a division of Ethicon, Inc., a Johnson & Johnson Company, 249 Vanderbilt Avenue, Norwood, MA 02062. In addition, the MINILOK QuickAnchor Plus is substantially equivalent to the absorbable Mini Bio-Anchor, K022234, manufactured by Arthrex, Inc., in Naples, Florida.

Device Classification

Bone anchors/screws are classified by FDA as a Class II Medical Devices under the generic category of Single/Multiple Component Metallic Bone Fixation Appliances, Orthopedic Devices Panel (reference 21 CFR §888.3030). Product code MAI.

Device Description	The MINILOK QuickAnchor Plus is preloaded disposable anchor/inserter assembly designed to facilitate the delivery and installation of the MINILOK QuickAnchor Plus into bone.
Indications for Use	The MINILOK QuickAnchor Plus is intended for fixation of soft tissue to bone, using suture, for the indications listed below: Ankle: Mid-foot reconstruction Foot: Hallux valgus reconstruction Hand: Ulnar or lateral collateral ligament reconstruction Wrist: Scapholunate ligament reconstruction
Safety	Biocompatibility studies have demonstrated the MINILOK QuickAnchor Plus to be non-toxic, non-irritating, non-sensitizing, and non-cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2003

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

Re: K030995
Trade/Device Name: MINILOK Anchor Plus
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 28, 2003
Received: March 31, 2003

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.

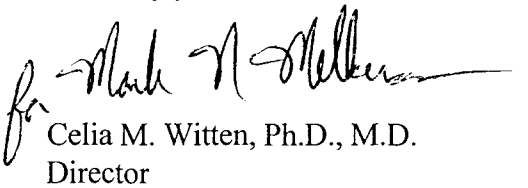
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

INDICATIONS FOR USE

510(k) Number (if known): K030995

Device Name: MINILOK QuickAnchor Plus

Indications for Use:

MINILOK QuickAnchor Plus is intended for fixation of soft tissue to bone, using suture, for the indications listed below:

Ankle: Mid-foot reconstruction
Foot: Hallux Valgus reconstruction
Hand: Ulnar or lateral collateral ligament reconstruction
Wrist: Scapholunate ligament reconstruction

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes or Over-the-Counter Use No

for Mark A. Milhem

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

510(k) Number K030995