K992623

NOV - 2 1999

510(k) Summary

Trade Name: **Mitek Mini Anchor**

Sponsor:
Mitek Products
60 Glacier Drive
Westwood, MA 02090
Registration #1221934

Contact:
Paula E. Bulger
Manager, Regulatory Affairs
Mitek Products
60 Glacier Drive
Westwood, MA 02090
Phone: (781) 251-2700
Fax: (781) 461-9166

Device Generic Name: Staple, Fixation, Bone

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Product Code: JDR (21 CFR 888.3030)

Predicate Devices:
K921873 - **Mitek Mini Anchor**
K930892 - **Mitek Mini Anchor**
K936311 - **Mitek Mini Anchor**

Product Description: The device described in this 510(k) is a sterile, disposable bone anchor consisting of a titanium alloy shaft with nickel-titanium shape-memory alloy arcs. The anchor is supplied pre-loaded with a polyester suture.

Indications for Use:
Mitek Mini Anchors have been found substantially equivalent in previous Premarket Notifications for the following indications:

Shoulder:	Bankart Repair
Ankle:	Midfoot Reconstructions
Foot:	Hallux Valgus Reconstruction
Wrist:	Scapholunate Ligament Reconstruction
Hand:	Ulnar or Lateral Collateral Ligament Reconstruction
Pubis:	Fixation in the pubis for bladder neck suspension to resolve stress urinary incontinence

This current 510(k) allows modification of the Mini Anchor labeling in order to add the following indication:

For the repair, repositioning or reattachment of soft tissues, ligament and tendons to the mandible for surgical stabilization of the TMJ articular disc.

Safety and Performance:
The following safety and performance data has been provided to support substantial equivalence of the Mini Anchor for the expanded indication:

Performance testing:	Pull-out force (preserved human cadaver mandibular condyle) Strength comparison (Mini Anchor vs. bone tunnels in fresh frozen human mandible)
Long-term stability:	Evaluation of osteointegration and positional stability in Mini Anchors used for new indication
Clinical data:	Long-term patient follow-up evaluation of Mini Anchors used for new indication

Conclusion:
Based on safety and performance data, similarities in design, operating principle, materials, biocompatibility and sterilization method, the Mitek Mini Anchor with expanded indication 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

NOV - 2 1999

Ms. Paula E. Bulger
Regulatory Affairs Manager
Mitek Products
Ethicon, Inc.
60 Glacier Drive
Westwood, MA 02090

Re: K992623

Trade Name: Mitek Mini Anchor
Regulatory Class: II
Product Code: DZL
Dated: August 4, 1999
Received: August 5, 1999

Dear Ms. Bulger:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992623

Device Name: Mitek Mini Anchor

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The Mitek Mini Anchor is also indicated for the repair, repositioning or reattachment of soft tissues, ligaments and tendons to the mandible for surgical stabilization of the TMJ articular disc.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

Susan Runyon

(Division **Sign-Off**)
Division of **Dental, Infection Control,**
and General **Hospital Devices**
510(k) Number K992623