K032078

AUG 2 5 2003

SECTION 2 – 510(k) SUMMARY

MITEK Micro QuickAnchor

Submitter's Name and Address:	MITEK Worldwide a Division of Ethicon Inc., a Johnson & Johnson Company 249 Vanderbilt Avenue Norwood, MA 02062
Contact Person	Sergio Gadaleta, PhD Manager, Regulatory Affairs MITEK Worldwide a Division of Ethicon Inc., a Johnson & Johnson Company 249 Vanderbilt Avenue Norwood, MA 02062 Telephone: 781-251-2018 Facsimile: 781-278-9578 e-mail: sgadalet@ethus.jnj.com
Name of Medical Device	Classification Name: Staple, Fixation, Bone Common/Usual Name: Suture Anchor Proprietary Name: Micro QuickAnchor
Substantial Equivalence	Micro Quick Anchor has been cleared by FDA: K962793, K962511, K982420
Device Classification	Suture Anchors are Class II devices.
Device Description	MITEK anchors are titanium alloy implants used to anchor or lock suture within bony sites for firmly securing soft-tissue to bone.

Indications for Use	MITEK Micro QuickAnchor is intended to attach suture into bone for the suspension of the nasal valve. MITEK Micro QuickAnchor is intended to attach suture into bone at the lower orbital rim.
Safety	This product has been cleared through pre-market notification: K962793, K962511, K982420. Safety data may be referenced in the 510(k) documents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2003

Mitek Worldwide
c/o Sergio J. Gadaleta
Manager, Regulatory Affairs
Division of Ethicon Inc.,
a Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, MA 02062

Re: K032078
Trade/Device Name: MITEK Micro QuickAnchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accesories
Regulatory Class: Class II
Product Code: NOV
Dated: June 26, 2003
Received: July 8, 2003

Dear Mr. Gadaleta:

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) 594-4613. 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 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,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(k) Number (if known): K032078

Device Name: MITEK Micro QuickAnchor

Indications for Use:

MITEK Micro QuickAnchor is intended to attach suture into bone for the suspension of the nasal valve.

MITEK Micro QuickAnchor is intended to attach suture into bone at the lower orbital rim.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises
510(k) Number K032078