JUN - 9 1997

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS K970896

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: Modified Mitek 3.5mm Absorbable Suture Anchor System

PREDICATE DEVICE NAME: Mitek 3.5mm Absorbable Suture Anchor System

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510(k) SUMMARY

Device Description

The Modified Mitek PANALOK 3.5mm Absorbable Suture Anchor System is designed to implant within a pre-drilled bone hole site and provide a means for firmly securing soft tissue to bone using sutures.

The Modified Mitek PANALOK 3.5mm Absorbable Suture Anchor System includes a PLL (homopolymer poly (L(-)-lactide) anchor pre-threaded with ETHICON Absorbable poly (L-lactide/glycolide) Surgical Suture, Undyed, two pre-attached surgical needles, and a pre-assembled disposable inserter. The system is supplied sterile and ready for use. Mitek instruments, drill and drill guide, are to be used to install the Mitek PANALOK 3.5mm Absorbable Suture Anchor. The drill bit creates a hole 3.5mm in diameter by 18mm deep.

Poly (L(-)-lactide) polymer is nonpyrogenic.

Intended Use

The Modified Mitek 3.5mm Absorbable Suture Anchor System is intended for use in soft tissue to bone fixation in association with adequate post-operative immobilization.

Indications Statement

The Mitek PANALOK 3.5mm Absorbable Anchor System is indicated for use in soft tissue to bone fixation in association with adequate post-operative immobilization as follows:

OPEN PROCEDURES

SHOULDER:

1. Bankart repair
2. SLAP lesion repair
3. Rotator cuff repair
4. a. Capsule shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus
   b. Capsule shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus
5. Biceps tenodesis
6. Acromio-clavicular separation

ELBOW:

1. Biceps tendon/reattachment

ANKLE:

1. Achilles tendon repair/reconstruction
2. Lateral stabilization
3. Medial stabilization at the medial talus site

KNEE:

1. Medial collateral ligament repair
2. Lateral collateral ligament repair
3. Join capsule closure to anterior proximal tibia
4. Posterior oblique ligament or joint capsule to tibia repair
5. Extra capsular reconstruction/ITB tenodesis
6. Patellar ligament and tendon avulsion repairs

Continued on next page

Indication Statement (continued) ARTHROSCOPIC PROCEDURES

SHOULDER:

1. Bankart repair
2. SLAP lesion repair
3. Rotator cuff repair
4. Capsule shift repair (glenoid rim)

Technological Characteristics

The modified device has the same technological characteristics as the predicate device. There are no changes in chemistry, material or composition. When compared to the predicate device, it only differs in that the ETHICON Absorbable poly (L-lactide/glycolide) Surgical Suture, Undyed is being attached to its anchor system.

Performance Data

Nonclinical laboratory testing was performed to assess the in vitro and in vivo strength and failure modes.

Conclusions

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the modified device is substantially equivalent to the predicate device under the Federal Food, Drug, and Cosmetic Act.

Contact

Gregory Jones
Director, Regulatory Affairs
ETHICON, Inc.
Rt. #22, West
Somerville, NJ 08876-0151

Date

March 10, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 1997

Mr. Gregory Jones
Director, Regulatory Affairs
Ethicon, Inc.
P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K970896
Trade Name: Mitek 3.5mm Panalok Wedge
Absorbable Suture Anchor System
Regulatory Class: II
Product Code: MAI
Dated: March 10, 1997
Received: March 11, 1997

Dear Mr. Jones:

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) 594-4659. 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" (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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K970896

Device Name: Modified Mitek 3.5mm PANALOK Wedge Absorbable Suture Anchor System

Indications for Use:

The Modified Mitek 3.5mm PANALOK Wedge Absorbable Suture Anchor System is indicated for use in soft tissue to bone fixation in association with adequate post operative immobilization as follows:

Open Procedures	Arthroscopic Procedures
Shoulder:	Shoulder:
1. Bankart repair	1. Bankart repair
2. Slap lesion repair	2. Slap lesion repair
3. Rotator cuff repair	3. Rotator cuff repair
4. a. Capsule shift/capsulo-labral reconstruction, at the anterior glenoid rim site	4. Capsule shift repair (glenoid rim)
b. Capsule shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus	
5. Biceps tenodesis	
6. Acromio-clavicular separation	

Elbow:
1. Bicep tendon reattachment

Ankle:
1. Achilles tendon repair/reconstruction
2. Lateral stabilization
3. Medial stabilization at the talus site

Knee:
1) Medial collateral ligament repair
2) Lateral collateral ligament repair
3) Joint capsule closure to the anterior proximal tibia
4) Posterior oblique ligament or joint capsule to tibia repair
5) Extra capsular reconstruction/ITB tenodesis
6) Patellar ligament and tendon avulsion repairs

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970896

(Optional Format 1-2-9G)