K040827 (pg 1 of 3)

SECTION 2 – 510(k) SUMMARY

APR 3 0 2004

Panalok Loop Anchor

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson Company 249 Vanderbilt Avenue Norwood, MA 02062
Contact Person	Allyson Barford Regulatory Affairs Associate DePuy Mitek a Johnson & Johnson Company 249 Vanderbilt Avenue Norwood, MA 02062 Telephone: 781-251-2794 Facsimile: 781-278-9578 e-mail: abarford@dpyus.jnj.com
Name of Medical Device	Classification Name: Screw, Fixation, Bone Staple Common/Usual Name: Appliance for reconstruction of bone to soft tissue Proprietary Name: Panalok Loop Anchor
Substantial Equivalence	The Panalok Loop Anchor is substantially equivalent to the BioKnotless Anchor (K002639) and has similar indications to PANALOK Anchor System (K970896) manufactured by DePuy Mitek, a Johnson & Johnson Company, 249 Vanderbilt Avenue, Norwood, MA 02062.
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 codes GAM and MAI.
Device Description	The PANALOK Loop Anchor System is a preloaded absorbable

disposable suture anchor/inserter assembly designed to allow soft tissue repair to bone. The absorbable poly lactic acid (PLA) anchor is the identical anchor as that of the BIOKNOTLESS Anchor in design, configuration and dimensions. The absorbable anchor is a one-piece suture anchor constructed of molded Poly(L-lactide) polymer.

Indications for Use

The Panalok Loop Anchor is indicated for use in soft tissue to bone fixation in association with adequate postoperative immobilization as follows:

OPEN PROCEDURES
SHOULDER
1. Bankart repair
2. SLAP lesion repair
3. Rotator cuff repair
4a. Capsule shift/capsulo-labral reconstruction, at the anterior glenoid rim site
4b. Capsule shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus
5. Biceps tenodesis
6. Acromio-clavicular separation
7. Deltoid repair

ELBOW
1. Biceps tendon reattachment
2. Tennis elbow repair

ANKLE
1. Achilles tendon repair/reconstruction
2. Lateral stabilization
3. Medial stabilization at the medial talus site
Foot: Hallux Valgus reconstruction
4. Midfoot reconstruction

KNEE
1. Medial collateral ligament repair
2. Lateral collateral ligament repair
3. Joint 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

ARTHROSCOPIC PROCEDURES
SHOULDER
1. Bankart repair
2. SLAP lesion repair
3. Rotator cuff repair

K040827 (pg 3 of 3)

	4. Capsule shift repair (glenoid rim)
Safety	Biocompatibility studies have demonstrated the Panalok Loop Anchor to be non-toxic, non-irritating, and non-cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2004

Ms. Allyson Barford
Regulatory Affairs Associate
DePuy Mitek
a Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K040827
Trade/Device Name: Panalok Loop Anchor
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM, MAI
Dated: March 22, 2004
Received: April 2, 2004

Dear Ms. Barford:

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.

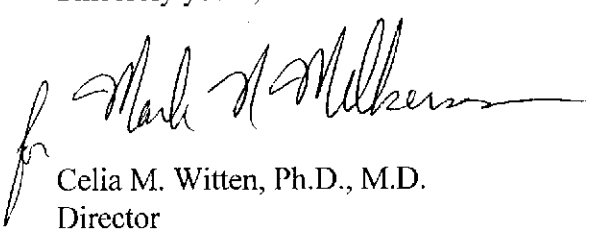
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4659. 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,



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 (pg 1 of 2)

510(k) Number (if known): K040827

Device Name: Panalok Loop Anchor

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Foot: Hallux Valgus reconstruction
4. Midfoot reconstruction

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

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

510(k) Number K040827

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