MAY - 4 2006

K060271

SECTION 6 – 510(k) SUMMARY

Submitter's Name and Address:

DePuy Mitek
a Johnson & Johnson company
325 Paramount Drive,
Raynham, MA 02767 USA

Contact Person

Ruth Forstadt, RAC
Project Management Lead, Regulatory Affairs
DePuy Mitek
a Johnson & Johnson company
325 Paramount Drive,
Raynham, MA 02767 USA
Telephone: (508) 977-3988
Facsimile: (508) 828-3750
e-mail: rforstad@dpyus.jnj.comT

Name of Medical Device

UUUUUUUUUUDevice Regulation:
Fastener, Fixation, Biodegradable, Soft Tissue
(21 CFR 888.3030)
Product code: 87 MAI

Common/Usual Name:
Biodegradable Fixation Fastener

Proprietary Name:
SpiraLok Anchor

Device Classification

In accordance with per 21 CFR 888.3030 suture anchors are classified by the FDA as Class II Medical Devices.

Indications for Use

The SpiraLok Anchor is intended for: **Shoulder:** Rotor Cuff Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair; **Foot/Ankle**: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair; **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; **Elbow:** Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

K06 0271

510(k) SUMMARY

Device Description

The SpiraLok Anchor is a PLA threaded suture anchor preloaded on a disposable inserter assembly intended for fixation of two strands of suture to bone. Ethibond non-absorbable suture, the Panacryl absorbable suture and the Orthocord composite suture options may include tapered needles to facilitate suture passage through tissue. The attached suture is then used to reattach soft tissue back to bone where it reconnects through the healing process.

Substantial Equivalence

The SpiraLok Anchor is a commercially marketed device that was subject of K041069 (cleared November 9, 2004). When used for the proposed indications the device is substantially equivalent to the Arthrex Bio-Corkscrew Suture Anchor (K003227, cleared 1/8/2001).

Safety and Performance

The determination of substantial equivalence for this device was based on a detailed device description. Non-clinical laboratory testing was performed demonstrating that the device is safe and can be considered substantially equivalent to the predicate Arthrex Bio-Corkscrew Suture Anchor for the proposed new intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Mitek
c/o Ms. Ruth Forstadt, RAC
Project Management Lead, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

MAY - 4 2006

Re: K060271
Trade/Device Name: SpiraLok Absorbable Threaded Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HWC, MAI
Dated: January 31, 2006
Received: February 1, 2006

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K060271

Device Name: SpiraLok Absorbable Threaded Suture Anchor

Indications For Use:

The Spiralok Anchor is intended for:

- **Shoulder:** Rotator Cuff Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair
- **Foot/Ankle**: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair
- **Knee**: Medial Collateral Ligamet Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
- **Elbow:** Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060271