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JUN -6 2006

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
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e-mail: rforstad@dpyus.jnj.com

Name of Medical Device

Device Regulation:
Fastener, Fixation, Non-Degradable, Soft Tissue
(21 CFR 888.3040)
Product code: 87 MBI

Common/Usual Name:

Proprietary Name:
FASTIN RC Anchor

Device Classification

In accordance with per 21 CFR 888.3040, suture anchors are classified by the FDA as Class II Medical Devices.

Indications for Use

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

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510(k) SUMMARY

Device Description

The FASTIN RC Anchor is a threaded titanium alloy implantable suture anchor preloaded on a disposable inserter assembly intended for fixation of two strands of suture. The anchors are made from Titanium 6A1-4V ELI per ASTM F- 136. The attached suture is then used to reattach soft tissue back to bone where it reconnects through the healing process. Once the tissue has healed (about six weeks) the anchor function is complete and the implant becomes dormant in the
The FASTIN RC Anchor is available in 5.0mm and 6.5mm sizes and is offered with three suture options, non-absorbable Ethibond, absorbable Panacryl, and composite Orthocord.

Substantial Equivalence

The FASTIN RC Anchor is a commercially marketed device that was originally subject of K983818 (cleared November 23, 1998). When used for the proposed indications the device is substantially equivalent to the FASTIN Anchor (K945203) and the Arthrex Titanium Corkscrew Anchor (K003816).

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 FASTIN 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

JUN - 6 2006

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

Re: K060664
Trade/Device Name: Fastin RC Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI
Dated: May 3, 2006
Received: May 5, 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K060664

Device Name: FASTIN RC Anchor

The FASTIN RC Anchors are indicated for the following:

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

Prescription Use ___√_ OR Over-the -Counter Use ___X___
(Per 21 CFR 801.109)

(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 K060664