K041075 Page 1 of 2

NOV - 9 2004

# SECTION 9 – 510(k) SUMMARY

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| **Submitter's Name and Address:** | DePuy Mitek<br>a Johnson & Johnson company<br>249 Vanderbilt Avenue<br>Norwood, MA 02062 |
| **Contact Person** | Allyson Barford<br>Regulatory Affairs Associate<br>DePuy Mitek<br>a Johnson & Johnson company<br>249 Vanderbilt Avenue<br>Norwood, MA 02062<br>Telephone: 781-251-2794<br>Facsimile: 781-278-9578<br>e-mail: abarford@dpyus.jnj.com |
| **Name of Medical Device** | Device Regulation:<br>Staple, Fixation, Bone<br>(21 CFR 888.3030)<br>Product codes: MBI, HWC, GAM and GAS<br><br>Common/Usual Name:<br>Staple, Fixation, Bone<br><br>Proprietary Name:<br>**Fastin RC Anchor** |
| **Device Classification** | Non-Absorbable Metal Suture Anchors carry FDA product codes MBI, HWC, GAM & GAS, and are classified as Staple, Fixation, Bone under 21 CFR 888.3030. |
| **Indications for Use** | The **Fastin RC** Anchor is intended for:<br>Shoulder: Rotator cuff repair. |
| **Device Description** | The Mitek **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 designed to be used in the surgical repair of the rotator cuff, and are made from Titanium 6Al-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 |

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| | bone. The proposed **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 changes being made from the predicate Fastin RC Anchor to the proposed **Fastin RC** Anchor are either dimensional or a material change. The dimensional change is minor (as described in detail in **Section 2** – Device Description) and does not affect the safety or effectiveness of the device. The second change is a material change to include a third suture option, composite Orthocord (K040004). Orthocord suture was previously cleared by FDA for use in general soft tissue approximation and/or ligation, including use in orthopedic surgeries. The addition of Orthocord suture option and the dimensional change made to the design of the anchor does not alter the intended use, safety and effectiveness or the fundamental scientific technology of the predicate devices.<br><br>Mitek believes that the **Fastin RC** Anchor is substantially equivalent to Mitek's existing Fastin RC Anchor (K983818).<br><br>A statement of substantial equivalence is provided in **Section 3** and the 510(k) "Substantial Equivalence" Decision-Making Process is attached in **Appendix III**. |
| **Safety and Performance** | The determination of substantial equivalence for this device was based on a detailed device description and changes that intend to be made to currently marketed devices. Non-clinical laboratory testing was performed demonstrating that the device is safe and performs as intended. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2004

Ms. Ruth C. Forstadt
Project Management Lead, Regulatory Affairs
Depuy Mitek
A Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K041075
Trade/Device Name: Fastin RC Anchors
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HWC, MAI
Dated: August 13, 2004
Received: August 16, 2004

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.

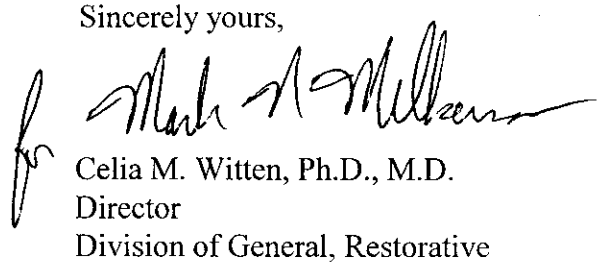
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number (if known): K041075

Device Name: Fastin RC Anchors

The **Fastin RC Anchors** are intended for:
Shoulder: Rotator cuff repair.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes (Per 21 CFR 801.109) OR Over-the -Counter Use No

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

510(k) Number K041075