MAR 11 2009

510(k) Summary

Gryphon P BR Anchor

Submitter's Name and Address:	DePuy Mitek, Inc. a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767, USA
Contact Person	Zheng Liu Regulatory Affairs Specialist DePuy Mitek, Inc. a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-977-3966 Facsimile: 508-977-6955 e-mail: zliu8@its.jnj.com
Name of Medical Device	Classification Name: Single/Multiple component metallic bone fixation appliances and accessories Common/Usual Name: Bone Anchor Proprietary Name: Gryphon P BR Anchor
Substantial Equivalence	The **Gryphon P BR Anchor** is substantially equivalent to the Gryphon BR Anchor (K073412, January 17, 2008).
Device Classification	Single/Multiple component metallic bone fixation appliances and accessories, classified as Class II, product code MAI and subsequent codes GAM, GAS and GAT, regulated under 21 CFR 888.3030.
Device Description	The **Gryphon P BR Anchor** is an absorbable suture anchor manufactured of "Biocryl Rapide" material. The anchor comes preloaded on a disposable inserter assembly and is intended for fixation of #2 suture to bone. The suture option is provided without needles. The Gryphon P BR Anchor is provided as size 3.0 mm.
Indications for Use	The **Gryphon P BR Anchor**, with ridged design, is intended for: **Shoulder:** Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid

	Repair, Capsular Shift or Capsulolabral Reconstruction; **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.
Safety and Performance	In support of the 510(k), Mitek has provided certification of compliance to 21 CFR 820.30 Design Control requirements, descriptions of Mitek's subcontractor Design Control and Risk Analysis procedures, and the results of validation testing (performance testing) for the device modification. Based on the Indications for Use, technological characteristics and safety and performance testing, the **Gryphon P BR Anchor** has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2009

DePuy Mitek, Inc.
% Ms. Zheng Liu
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K090124
Trade/Device Name: Gryphon P BR Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulation Class: Class II
Product Code: MAI
Dated: February 18, 2009
Received: February 20, 2009

Dear Ms. Liu:

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.

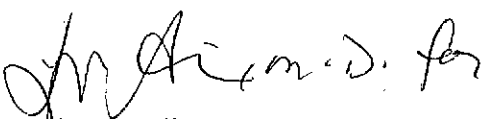
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



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): K090124

Device Name: Gryphon P BR Anchor

Indications For Use:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;

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.

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

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

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