SECTION 2 – 510(k) SUMMARY

JAN 17 2008

Healix BR and Gryphon BR Anchor

Submitter's Name and Address:

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

Contact Person

Ruth C. Forstadt
Project Manager, Regulatory Affairs
DePuy Mitek
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Raynham, MA 02767
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Name of Medical Device

Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue Smooth or threaded metallic bone fixation fasteners
Common/Usual Name:	Bone Anchor
Proprietary Name:	Healix BR and Gryphon BR Anchor

Substantial Equivalence

Healix BR and Gryphon BR Anchors are substantially equivalent to:

Mitek Healix PEEK Anchor (K071481); BioKnotless/Lupine BR Anchors (K070925), the Arthrex Biocomposite Suture Anchor Family (K071177), and the Milagro Interference Screws (K032717 and K060830).

Device Classification

This device carries an FDA product code MAI, and subsequent product codes GAM, GAS and GAT, and is classified as Single/Multiple component metallic bone fixation appliances and fasteners under 21 CFR 888.3030.

Device Description

The Healix BR and Gryphon BR Anchors are absorbable threaded suture anchors manufactured of "Biocryl Rapide" material. The threaded anchor comes preloaded on a disposable inserter assembly and

	is intended for fixation of #2 suture to bone. The Healix BR Anchor is provided in three sizes: one with an outer diameter of 4.5mm, another with an outer diameter of 5.5mm and the third with an outer diameter of 6.5mm. The Gryphon BR Anchor is provided as size 3.0mm. The suture options may or may not include tapered needles to facilitate suture passage through tissue. The Healix BR and Gryphon BR Anchors are currently offered with absorbable Panacryl, non-absorbable Ethibond or partially absorbable Orthocord suture options.
Indications for Use	**The Healix BR and Gryphon BR Anchors** are intended for: **Shoulder:** Rotor 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	Results of performance and safety testing have demonstrated that the modified device is substantially equivalent to the predicate devices. Based on the indications for use, technological characteristics, and comparison to predicate devices, the Healix BR and Gryphon BR Anchors have 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

JAN 17 2008

DePuy Mitek, a Johnson & Johnson Company
% Ruth C. Forstadt, RAC
Project Manager, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K073412
Trade/Device Name: Gryphon BR and Healix BR Anchors
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI
Dated: January 10, 2008
Received: January 11, 2008

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 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

510(k) Number (if known): K073412

Device Name: **Gryphon BR Anchor**

Gryphon BR Anchor is indicated for use in the following:

Shoulder: Rotor 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 ___√___ 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 K073412

510(k) Number (if known): K073412

Device Name: **Healix BR Anchor**

Healix BR Anchor is indicated for use in the following:

Shoulder: Rotor 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 ___√___ OR Over-the -Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruehup

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

510(k) Number K073412