K103712
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510(k) SUMMARY

MAR 1 1 2011

Gryphon PEEK Anchor

Submitter's Name and Address:

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

Contact Person

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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: Gryphon PEEK Anchor

Substantial Equivalence

Gryphon PEEK Anchors are substantially equivalent to:

- K100012 Gryphon BR Anchor -Hip (April 30, 2010)
- K090124 Gryphon P BR Anchor (March 11, 2009);
- K071481 Healix Peek Anchor (August 9, 2007)
- K102298 TransTend Anchor (January 7, 2011)
- K073412 Gryphon BR and Healix BR Anchor (January 17, 2008)

Device Classification

This device carries an FDA product code HWC and is classified as Single/Multiple component metallic bone fixation appliances and fasteners under 21 CFR 888.3030. This device is offered with Orthocord suture (K040004, K043298).

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Device Description	The Gryphon PEEK Anchors are non-absorbable threaded suture anchors manufactured of PEEK material. The barbed anchor comes preloaded on a disposable inserter assembly and is intended for fixation of #2 suture to bone. The Gryphon PEEK Anchor is provided as size 3.0mm. The Gryphon PEEK Anchors will be offered with partially absorbable Orthocord suture options, similar to the Gryphon P BR Anchor. Technologies characteristics including design and packaging are the same as the predicate cleared devices.
Indications for Use	**The GRYPHON PEEK Anchor is intended for:** **Shoulder:** Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction; **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; **Elbow:** Ulnar or Radial Collateral Ligament Reconstruction; **Hip:** Capsular Repair, Acetabular Labral Repair.
Non clinical Testing	Verification activities were performed on the implant or its predicates. Testing assessments include pull out testing, shelf-life, sterilization and biocompatibility.
Safety and Performance	Results of performance and safety testing have demonstrated that the modified device is substantially equivalent to the predicate devices. Gryphon PEEK Anchors are similar to: Gryphon P BR Anchor (K100012, K090124), Healix Peek Anchor (K071481) and TransTend Anchor (102298). Based on the indications for use, technological characteristics, and comparison to predicate devices, the Gryphon PEEK 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Mitek
% Ms. Kristine Christo
Project Manager, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

MAR 11 2011

Re: K103712
Trade/Device Name: Gryphon PEEK 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
Dated: December 17, 2010
Received: December 20, 2010

Dear Ms. Christo:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103712

Device Name: Gryphon PEEK Anchor

Indications for Use:

The GRYPHON PEEK Anchor is intended for:

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

Foot/Ankle: Lateral Stabilization, Medial Stabilization,

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis;

Elbow: Ulnar or Radial Collateral Ligament Reconstruction;

Hip: Capsular repair, acetabular labral repair.

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

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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