JUN 10 2014

SECTION 2 - 510(k) SUMMARY

Gryphon™ Anchor with Permacord™

Submitter's Name and Address	DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767 Date Prepared: May 14, 2014
Contact Person	Julie Vafides Regulatory Affairs Specialist DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-977-6645 Facsimile: 508-977-6911 e-mail: jvafides@its.jnj.com
Name of Medical Device	Proprietary Name: a) Gryphon™ BR Anchor with Permacord™ b) Gryphon™ PEEK Anchor with Permacord™ Classification Name: a) Single/multiple component metallic bone fixation appliances and accessories b) Smooth or threaded metallic bone fixation fasteners Common Name: Suture Anchor
Substantial Equivalence	The Gryphon™ Anchor with Permacord™ is substantially equivalent to: ▪ K090124, K100012 Gryphon™ P BR Anchor with Orthocord® ▪ K103712 Gryphon™ PEEK Anchor with Orthocord® ▪ K133794 Healix Advance™ Anchor with Permacord™
Device Classification	➢ Gryphon™ BR Anchors with Permacord™ are classified as: Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, product code MAI, regulated under 21 CFR 888.3030. ➢ Gryphon™ PEEK Anchors with Permacord™ are classified as: Smooth or threaded metallic bone fixation fasteners, classified as Class II, product code MBI, regulated under 21 CFR 888.3040.

Device Description	The Gryphon™ Anchor with Permacord™ is a suture anchor preloaded on a disposable inserter assembly intended for fixation of suture to bone. Gryphon Anchors are available in absorbable BR and non-absorbable PEEK materials. Permacord suture is non-absorbable. The Gryphon Anchor with Permacord suture is supplied sterile and is for single use only.
Technological Characteristics	The proposed Gryphon Anchors with Permacord suture have the same anchor materials and design as predicate Gryphon Anchors (K090124, K100012, K103712). The proposed device principal operation is the same as predicate Gryphon Anchors (K090124, K100012, K103712). The Permacord suture is the same suture as referenced in predicate Healix Advance™ Anchor with Permacord™ (K133794).
Indications for Use	The ***GRYPHON BR Anchor*** 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 Hip: Capsular Repair, Acetabular Labral Repair 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 and / or its predicates. Testing assessments include pull out testing and in-vitro testing.
Safety and Performance	Results of performance testing have demonstrated that the proposed devices are suitable for their intended use. Based on similarities in the indications for use, technological characteristics, and performance in comparison to the predicate devices, the proposed Gryphon Anchor with Permacord suture has shown to be substantially equivalent to the 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 Center - WO66-G609
Silver Spring, MD 20993-0002

June 10, 2014

DePuy Mitek, Incorporated
Ms. Julie Vafides
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K141259
Trade/Device Name: Gryphon™ BR and PEEK with Permacord™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: May 14, 2014
Received: May 15, 2014

Dear Ms. Vafides:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Lori A. Wiggins

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141259

Device Name
Gryphon BR and PEEK with Permacord

Indications for Use *(Describe)*

The GRYPHON BR Anchor 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
Hip:	Capsular Repair, Acetabular Labral Repair

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices