DePuy Synthes
MITEK SPORTS MEDICINE
COMPANIES OF Johnson & Johnson

JUL 08 2014

510(k) SUMMARY
GRYPHON™ ANCHOR w/PROKNOT™ TECHNOLOGY

Date Summary Prepared	May 2, 2014	
Submitter's Name and Address	DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767	
Contact Person	Yayoi Fujimaki Regulatory Affairs Senior Associate DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA	Telephone: 508-828-3541 Facsimile: 508-977-6911 e-mail: yfujima1@its.jnj.com
Name of the Device	Trade Name: GRYPHON™ Anchor w/PROKNOT™ Technology Common Name: fastener, fixation, biodegradable, soft tissue	
Device Classification	▪ MAI - Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, regulated per 21 CFR 888.3030. ▪ MBI - Smooth or threaded metallic bone fixation fastener, classified as Class II, regulated per 21 CFR 888.3040. ▪ Orthopedic panel	
Predicate Device	The proposed device is substantially equivalent to: ▪ GRYPHON™ Anchor w/PROKNOT™ Technology (K132241); ▪ GRYPHON BR Anchor (K100012, K090124); ▪ GRYPHON PEEK Anchor (K103712). The following predicate devices were referenced: ▪ Healix Advance Anchor w/Permacord suture (K133794); ▪ Force Fiber Blue Polyethylene Non-Absorbable Surgical Suture (K092533, Teleflex Medical Incorporated)	
Indications for Use	Shoulder: Bankart Repair, SLAP Lesion Repair, Capsular Shift or Capsulolabral Reconstruction Hip: Capsular Repair, Acetabular Labral Repair	

Device Description	The proposed device is a suture-anchor to be used for soft tissue fixation to bone. The Gryphon Anchor is a cannulated, ribbed anchor, made of either non-absorbable PEEK (Polyetheretherketone) or absorbable Biocryl® Rapide™ (composite of β-TCP and PLGA copolymer). Size #1 blue Permacord™ suture (UHMWPE braided suture) is preloaded on the anchor. The suture incorporates a pre-tied sliding knot (ProKnot knot). The Permacord suture is a non-absorbable suture that conforms to USP except for oversized diameter. The device is provided as sterile; the device is for single patient use only.
Comparison of Technological Characteristics	The anchors are existing Gryphon anchors. The blue #1 Permacord suture is made from the same materials as the blue #2 Permacord suture that is used for the Healix Advance Anchor w/Permacord suture. No other new technological characteristics are introduced to the proposed device compared with the predicate device. Fixation strength testing ensured substantial equivalence of device performance. No new issue of safety and efficacy has been raised.
Safety and Performance	**Non-clinical Testing** Fixation strength testing, suture knot strength testing and suture fray testing were conducted and the data were compared with the data of the predicate devices. The data demonstrated substantial equivalence of product performance. The proposed device has raised no new issue of safety and efficacy. Suture testing on the Permacord suture was also conducted per USP.
Substantial Equivalence	Based on technological characteristics comparison and performance evaluation, the proposed device is concluded to be substantially equivalent to the predicate device.

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

July 8, 2014

DePuy Mitek
Ms. Yayoi Fujimaki
Senior Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K140643
Trade/Device Name: Gryphon Anchor w/ProKnot Technology
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: June 3, 2014
Received: June 5, 2014

Dear Ms. Fujimaki:

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" (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 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)*

K140643

Device Name
Gryphon Anchor w/ProKnot Technology

Indications for Use *(Describe)*

Gryphon Anchor w/ProKnot Technology is indicated for followings.

Shoulder: Bankart Repair, SLAP Lesion Repair, Capsular Shift or Capsulolabral 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