FEB - 4 2014

SECTION 2 - 510(k) SUMMARY

Healix Advance™ Anchor with Permacord™

Submitter's Name and Address	DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767 Date Prepared: December 11, 2013
Contact Person	Tatyana Korsunsky Regulatory Affairs Specialist DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-828-3122 Facsimile: 508-977-6911 e-mail: tkorsuns@its.jnj.com
Name of Medical Device	Proprietary Name: a) Healix Advance™ BR Anchor with Permacord™ b) Healix Advance™ 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 Healix Advance™ Anchor with Permacord™ is substantially equivalent to: ▪ K120078 Healix Advance™ BR Anchor with Orthocord® suture ▪ K120449 Healix Advance™ PEEK Anchor with Orthocord® suture ▪ K100012, K073412 Gryphon™ T BR Anchor with Orthocord® suture The following predicate devices were referenced: • K070673 Force Fiber® White/Black Co-Braid, Teleflex • K092533 Force Fiber® Blue Braid, Teleflex • K100506 Force Fiber® White/Green Co-Braid, Teleflex
Device Classification	➢ Healix Advance BR anchor is classified as: Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, product code MAI, regulated under 21 CFR 888.3030. ➢ Healix Advance PEEK anchor is classified as: Smooth or threaded metallic bone fixation fasteners, classified as Class II, product code HWC, regulated under 21 CFR 888.3040.

Device Description	The Healix Advance™ Anchor with Permacord™ suture is a threaded suture anchor preloaded on a disposable inserter assembly intended for fixation soft tissue to bone. Healix Advance Anchors are available in absorbable BR and non-absorbable PEEK materials. Permacord suture is a non-absorbable suture that conforms to USP, except for oversized diameter. Healix Advance Anchors with Permacord are provided sterile and is for single use only.
Technological Characteristics	The proposed Healix Advance Anchors with Permacord suture have the same anchor materials and design as predicate Healix Advance Anchors (K120078, K120449). The proposed device principal operation is the same as predicate Healix Advance Anchors (K120078, K120449) and Gryphon™ BR (K100012) anchors. The Permacord suture has the same design and materials as Teleflex's Force Fiber suture (K070673, K092533, K100506), and conforms to USP, except for oversized diameter.
Indications for Use	The HEALIX ADVANCE Anchor is indicated for use in soft tissue to bone fixation in association with post-operative immobilization as follows: **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.
Non clinical Testing	Verification activities were performed on the implant and / or its predicates. Testing assessments include pull out testing, insertion and failure torque, *in-vitro* testing and suture testing per USP.
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 Healix Advance 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

February 4, 2014

DePuy Mitek, a Johnson & Johnson company
Ms. Tatyana Korsunsky
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K133794
Trade/Device Name: Healix Advance™ Anchor with Permacord™ suture
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, HWC
Dated: December 11, 2013
Received: December 13, 2013

Dear Ms. Korsunsky:

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 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. 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 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,

Vincent D Devlin -S

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

Enclosure

Indications for Use

510(k) Number (if known): K133794

Device Name: Healix Advance™ Anchor with Permacord™ suture

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Elbow:	Biceps Tendon Reattachment, 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)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices