DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Medos International SARL
% Ms. Julie Vafides
Project Lead, Regulatory Affairs
Depuy Mitek, a Johnson and Johnson Company
325 Paramount Drive
Raynham, Massachusetts 02767

May 18, 2017

Re: K170639
Trade/Device Name: HEALIX ADVANCE™ Anchor with PERMATAPE™ 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, MBI
Dated: February 28, 2017
Received: March 2, 2017

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,

Mark N. Melkerson -S

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)*

K170639

Device Name
HEALIX ADVANCE™ Anchor with PERMATAPE™ Suture

Indications for Use *(Describe)*

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 Collateral Ligament Reconstruction , 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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

HEALIX ADVANCE™ Anchor with PERMATAPE™ Suture

Submitter's Name and Address

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

Date Prepared: February 28, 2017

Contact Person

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Name of Medical Device

Proprietary Name:
a) HEALIX ADVANCE™ BR Anchor with PERMATAPE™ Suture
b) HEALIX ADVANCE™ PEEK Anchor with PERMATAPE™ Suture

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 PERMATAPE™ Suture is substantially equivalent to:

- K133794 HEALIX ADVANCE™ Anchor with PERMACORD™ Suture
- K100012, K073412 Gryphon™ BR Anchor with Orthocord® Suture

Reference devices:

- K162247 PERMATAPE™ Suture
- K120449 HEALIX ADVANCE™ PEEK Anchor

Device Classification

- HEALIX ADVANCE™ BR Anchor with PERMATAPE™ Suture 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 with PERMATAPE™ Suture is 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 HEALIX ADVANCE™ Anchor with PERMATAPE™ Suture consists of a threaded suture anchor preloaded on a disposable inserter assembly intended for fixation of one strand of #2 PERMACORD™ suture and one strand of PERMATAPE™ suture to bone. HEALIX ADVANCE™ Anchors with PERMATAPE™ are available in absorbable BR and non-absorbable PEEK materials. Devices with needles will be offered to facilitate suture passage through tissue. The HEALIX ADVANCE™ Anchor with PERMATAPE™ Suture is provided sterile and is for single use only.
Technological Characteristics	The proposed HEALIX ADVANCE™ Anchors with PERMATAPE™ Suture are similar to the predicate HEALIX ADVANCE™ Anchors with PERMACORD™ Suture (K133794) in that they share the same intended use, anchor design and materials, PERMACORD suture design and materials, device assembly, sterilization method, and shelf life. The proposed devices are similar to the predicate Gryphon™ BR Anchor with Orthocord® Suture in that they share the same indications for use, same anchor materials, similar anchor / device assembly design and principle of operation. The proposed devices are similar to the reference device, PERMACORD™ Suture (K162247), in that they share the same suture design and material. The proposed devices are similar to the reference device, HEALIX ADVANCE™ PEEK Anchor (K120449), in that both are offered with or without needles to facilitate suture passage through tissue.
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 Collateral Ligament Reconstruction , Radial Collateral Ligament Reconstruction **Hip:** Capsular Repair, Acetabular Labral Repair
Non clinical Testing	Verification activities were performed on the proposed device and / or its predicates. Testing assessments include pull out testing, insertion and failure torque and *in-vitro* testing.
Safety and Performance	Results of performance testing have demonstrated that the proposed devices are suitable for their intended use. Bacterial endotoxin testing has been completed and results have demonstrated that the proposed devices meet the endotoxin limits. Based on similarities in the indications for use, technological characteristics, and performance in comparison to the predicate devices, the proposed HEALIX ADVANCE™ Anchor with PERMATAPE™ Suture has shown to be substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.