February 14, 2019

Medos International SARL
% Tatyana Korsunsky
Regulatory Affairs Project Manager
DePuy Mitek, a Johnson and Johnson company
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K183506
Trade/Device Name: HEALIX ADVANCE™ Anchor with DYNACORD™ 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: December 17, 2018
Received: December 18, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -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)_
K183506

Device Name
HEALIX ADVANCE™ Anchor with DYNACORD™ 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)**

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
SECTION 2 - 510(k) SUMMARY
HEALIX ADVANCE™ Anchor with DYNACORD™ Suture

Submitter’s Name and Address
DePuy Mitek
325 Paramount Drive
Raynham, MA 02767

Contact Person
Tatyana Korsunsky
Regulatory Affairs Project Manager
DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767, USA

Name of Medical Device
Proprietary Name:
a) HEALIX ADVANCE™ BR Anchor with DYNACORD™ Suture
b) HEALIX ADVANCE™ PEEK Anchor with DYNACORD™ 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 DYNACORD™ Suture is substantially equivalent to:
▪ K173859 HEALIX ADVANCE™ Anchor with DYNACORD™ Suture

Reference devices:
▪ K021434, K041553 FiberWire® (Arthrex)
▪ K133794 HEALIX ADVANCE™ Anchors with PERMACORD™ Suture

Device Classification
➢ HEALIX ADVANCE™ BR Anchor with DYNACORD™ 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 DYNACORD™ 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 DYNACORD™ Suture is a threaded suture anchor preloaded on a disposable inserter assembly. HEALIX ADVANCE™ Anchors with DYNACORD™ Suture 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 DYNACORD™ Suture is provided sterile and is for single use only.

**Technological Characteristics**
The HEALIX ADVANCE™ Anchor with DYNACORD™ Suture is intended for fixation of soft tissue to bone, where anchor is inserted into the bone and sutures are utilized to hold soft tissue.

When DYNACORD™ Suture is placed in an aqueous environment, the salt particles within the silicone core elute out, leaving behind a micro-porous structure within the silicone core. These small voids are consequently filled with surrounding fluid as the core hydrates, resulting in a radial expansion of the suture. If laxity is present, this radial expansion of the braid causes an axial shortening of the total suture length. The DYNACORD™ Suture is designed to resist laxity and minimize gap formation, by maintaining approximation force (compression).

**Comparison to the Predicate Devices**
The proposed HEALIX ADVANCE™ Anchor with DYNACORD™ Suture is an update to the predicate HEALIX ADVANCE™ Anchor with DYNACORD™ Suture (K173859). The outer sheath of white/black DYNACORD is updated with black UHMWPE, and removal of black Nylon.

**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**
Device safety and effectiveness is supported by non-clinical testing on the proposed device and / or its predicate. Testing included suture diameter, knot tensile, suture approximation force and chemical characterization. Anchor fixation, in-vitro anchor fixation, torque testing, in-vivo testing, biocompatibility, sterility, packaging, shelf-life, and bacterial endotoxin testing of the predicate device were included by reference (K173859).
| Safety and Performance | Results of performed testing have demonstrated that the proposed device is suitable for its intended use. Based on the similarities in the indications for use, technological characteristics, and performance in comparison to the predicate devices, the proposed HEALIX ADVANCE™ Anchor with DYNACORD™ Suture has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act. |

---