February 21, 2019

Medos International SARL
% Leslie Coney
Regulatory Affairs Specialist
DePuy Mitek, a Johnson & Johnson Company
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K183279
Trade/Device Name: HEALIX Ti™ ANCHOR with DYNACORD™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: November 19, 2018
Received: November 23, 2018

Dear Leslie Coney:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183279

Device Name
HEALIX Ti™ ANCHOR with DYNACORD™

Indications for Use *(Describe)*
The HEALIX Ti™ Anchors with DYNACORD™ is intended for:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromioclavicular; 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, Patellar Tendon repair and secondary fixation in ACL/PCL reconstruction repair;

Elbow: Biceps Tendon Reattachment, 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) SUMMARY

HEALIX Ti™ Anchor with DYNACORD™ Suture

Date Prepared: January 23, 2019

Submitter's Name and Address	DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767

Contact Person	Leslie Coney Regulatory Affairs Specialist DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-977-2618 e-mail: lconey@its.jnj.com

Name of Medical Device	Proprietary Name:	-HEALIX TI™ ANCHOR with DYNACORD™ -HEALIX TI™ 3 SUTURE ANCHOR with DYNACORD™ -HEALIX TI™ ANCHOR with DYNACORD™ AND NEEDLES
	Classification Name:	Smooth or threaded metallic bone fixation fasteners
	Common Name:	Suture Anchor

Substantial Equivalence

The HEALIX Ti™ Anchor with DYNACORD™ Suture is substantially equivalent to:

- K082282 HEALIX Ti® Anchor with ORTHOCORD®

Reference devices:

- K173859 HEALIX ADVANCE® Anchors with DYNACORD® Suture
- K021434, K041553 FIBERWIRE® (Arthrex)
- K181809 GRYPHON ANCHOR® with DYNACORD®
- K082282 DYNACORD®

Device Classification

- HEALIX Ti™ Anchor with DYNACORD™ Suture is classified as:

  Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, product code MBI, regulated under 21 CFR 888.3040.

  Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, product code HWC, regulated under 21 CFR 888.3040.

Device Description	The HEALIX Ti™ Anchor with DYNACORD™ Suture is a threaded suture anchor preloaded on a disposable inserter assembly intended for fixation of soft tissue to bone. HEALIX Ti™ Anchors with DYNACORD™ Suture is available in Titanium material, which is a common material used on existing Depuy Mitek devices. Devices with needles will be offered to facilitate suture passage through tissue. The HEALIX Ti™ Anchor with DYNACORD™ Suture is provided sterile and is for single use only.
Technological Characteristics	The proposed HEALIX Ti™ Anchor with DYNACORD™ Suture has the same anchor materials, design, principle of operation, as well as device assembly, sterilization method, and shelf life, as predicate HEALIX Ti™ Anchor with ORTHOCORD® Suture (K082282). The DYNACORD® Suture component is a non-absorbable suture that conforms to USP, except for oversized diameter.
Indications for Use	The HEALIX Ti™ Anchors with DYNACORD™ 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, Patella tendon repair and secondary fixation in ACL / PCL reconstruction repair. **Elbow**: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction. **Hip**: Capsular repair, acetabular labral repair
Non clinical Testing	Non-clinical testing has been performed on the proposed device and /or its predicates. Performance testing included anchor fixation testing, torque testing, suture testing per USP and approximation force testing. Safety evaluations were conducted to address biological, sterility, packaging and shelf-life testing. Bacterial endotoxin testing has been completed and results have demonstrated that the proposed devices meet the endotoxin limits.
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 Ti™ Anchor with DYNACORD™ Suture has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.