February 1, 2021

Medos International SARL
℅ Elizabeth Messana
Regulatory Affairs Specialist II
Depuy Synthes Mitek, a Johnson & Johnson Company
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K203794
Trade/Device Name: HEALIX Ti™ Dual Threaded Suture Anchor with DYNATAPE™ Suture
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 30, 2020
Received: January 4, 2020

Dear Elizabeth Messana:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K203794

Device Name
HEALIX Ti™ Dual Threaded Suture Anchor with DYNATAPE™ Suture

Indications for Use *(Describe)*

The HEALIX Ti™ Dual Threaded Suture Anchor is intended for soft-tissue-to-bone fixation in association with postoperative immobilization.

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.

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.

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510(K) SUMMARY

HEALIX Ti™ Dual Threaded Suture Anchor with DYNATAPE™ Suture

Date Prepared: 12/21/2020

Submitter's Name and Address

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

On behalf of:
Medos International SARL
Chemin-Blanc 38, Le Locle Neuchatel
CH 2400, Switzerland

Contact Person

Elizabeth Messana
Regulatory Affairs Specialist II

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

Name of Medical Device

Trade Name / Proprietary Name:
HEALIX Ti™ Dual Threaded Suture Anchor with DYNATAPE™ Suture

Common Name:
Suture Anchor

Substantial Equivalence	The HEALIX Ti™ Dual Threaded Suture Anchor with DYNATAPE™ Suture is substantially equivalent to the predicates: • K183279, HEALIX Ti™ ANCHORS with DYNACORD™ Suture (Primary Predicate) • K200949, HEALIX ADVANCE™ Anchor with DYNATAPE™ Suture (Reference Predicate)
Device Classification	HEALIX Ti™ Dual Threaded Suture Anchor with DYNATAPE™ 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 Panel	Orthopedic Devices
Device Description	The proposed HEALIX Ti™ Dual Threaded Suture Anchor with DYNATAPE™ Suture is a line extension to the currently marketed HEALIX Ti™ Anchor family. The HEALIX Ti Anchor is a non-absorbable dual threaded suture anchor comprised of Titanium material. The threaded anchor comes preloaded on a disposable inserter assembly and is intended for fixation of one strand of #2 DYNACORD Suture and one strand of 2.5 mm DYNATAPE Suture to bone. The HEALIX Ti™ Dual Threaded Suture Anchor with DYNATAPE™ Suture is provided sterile via Ethylene Oxide (EO) sterilization and is for single use only.
Technological Characteristics	The suture anchor design and principal of operation are identical to the predicate device HEALIX Ti™ ANCHORS with DYNACORD™ Suture (K183279), while the indications for use are similar to the predicate as only a subset is pursued.

Indications for Use	The HEALIX Ti™ Dual Threaded Suture Anchor is intended for soft-tissue-to-bone fixation in association with postoperative immobilization. • 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.
Non-clinical Testing	Verification activities were performed on the proposed device and its predicates. Performance testing included evaluation of fixation strength following cyclic loading, knot tensile strength and suture approximation testing. Ethylene Oxide Sterilization was validated according to ANSI/AAMI/ISO 11135: 2014 to a SAL of 1×10^{-6}. EO residuals were tested per AAMI/ANSI/ISO 10993-7:2008 The proposed device has been determined to be non-pyrogenic per the requirements set forth in ANSI/AAMI ST-72:2011, United States Pharmacopeia (USP), and European Pharmacopeia (EP) using the bacterial endotoxin testing (BET) method.
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™ Dual Threaded Suture Anchor with DYNATAPE™ Suture has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.