June 28, 2019

Medos International SARL
% Ashley Goncalo
Project Manager - Regulatory Affairs
DePuy Synthes Mitek, a Johnson and Johnson Company
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K191483
Trade/Device Name: HEALIX ADVANCE™ Anchor with DYNA+TAPE™ Sutures
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, MAI
Dated: June 3, 2019
Received: June 4, 2019

Dear Ashley Goncalo:

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,

Laurence D. Coyne, 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)*
K191483

Device Name
HEALIX ADVANCE™ Anchor with DYNA+TAPE™ Sutures

Indications for Use *(Describe)*
The HEALIX ADVANCE Anchor with DYNA+TAPE Sutures 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

HEALIX ADVANCE™ Anchor with DYNA+TAPE™ Sutures

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	Ashley Goncalo Project Manager, Regulatory Affairs DePuy Synthes Mitek Sports Medicine *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767 Telephone: 508-977-3907 Email: agoncalo@its.jnj.com
Name of Medical Device	Proprietary Name: HEALIX ADVANCE Anchor with DYNA+TAPE Sutures a) HEALIX ADVANCE BR Anchor with DYNA+TAPE Sutures b) HEALIX ADVANCE PEEK Anchor with DYNA+TAPE Sutures 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 DYNA+TAPE Sutures is substantially equivalent to the predicates: • K170639 - HEALIX ADVANCE Anchor with PERMATAPE™ Suture (Primary) • K173859 - HEALIX ADVANCE Anchor with DYNACORD™ Suture
Device Classification	a) HEALIX ADVANCE BR Anchor with DYNA+TAPE Sutures 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.

	b) HEALIX ADVANCE PEEK Anchor with DYNA+TAPE Sutures 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 DYNA+TAPE Sutures is a threaded suture anchor preloaded on a disposable inserter assembly intended for soft tissue fixation with one strand of #2 DYNACORD Suture and one strand of PERMATAPE Suture to bone. HEALIX ADVANCE with DYNA+TAPE Anchors are available in absorbable Biocryl Rapide® (BR) and non-absorbable PEEK materials. The HEALIX ADVANCE with DYNA+TAPE Sutures is provided sterile and is for single use only.
Technological Characteristics	The proposed HEALIX ADVANCE Anchor with DYNA+TAPE Sutures has the same anchor materials, design, principle of operation, intended use, sterilization method, and shelf life, as the predicate HEALIX ADVANCE with DYNACORD Anchors (K173859) and the predicate HEALIX ADVANCE with PERMATAPE Anchors (K170639). The PERMATAPE Suture, which is preloaded on the proposed anchor, is identical to the PERMATAPE Suture which is preloaded on the predicate HEALIX ADVANCE with PERMATAPE Suture (K170639). The DYNACORD Suture, which is preloaded on the proposed anchor, is identical to the suture that is pre-loaded on the predicate HEALIX ADVANCE with DYNACORD Suture (K173859).
Indications for Use	The HEALIX ADVANCE Anchor with DYNA+TAPE Sutures 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. Performance testing included evaluation of fixation strength following cyclic loading.

	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 ADVANCE with DYNA+TAPE Anchors has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.