August 7, 2020

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

Re: K201883
Trade/Device Name: 6.5 mm HEALIX ADVANCE™ SP PEEK Anchor, 6.5 mm HEALIX ADVANCE™ SP BIOCOMPOSITE Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, MAI
Dated: July 7, 2020
Received: July 8, 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,

for

Laura C. Rose, Ph.D.
Acting 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)*
K201883

Device Name

HEALIX ADVANCE™ SP PEEK Anchor
HEALIX ADVANCE™ SP Biocomposite Anchor

Indications for Use *(Describe)*

The HEALIX ADVANCE SP PEEK Anchor is indicated for use in the following procedures for reattachment of soft tissue to bone:

Shoulder:	Rotator cuff repair, biceps tenodesis, deltoid repair
Knee:	Posterior oblique repair, medial collateral ligament (MCL) reconstruction, lateral collateral ligament reconstruction, iliotibial (IT) band tenodesis
Foot/Ankle:	Achilles tendon repair

The HEALIX ADVANCE SP Biocomposite Anchor is indicated for use in the following procedures for reattachment of soft tissue to bone:

Shoulder:	Rotator cuff repair, biceps tenodesis, deltoid repair
Knee:	Posterior oblique repair, medial collateral ligament (MCL) reconstruction, lateral collateral ligament reconstruction, iliotibial (IT) band tenodesis
Foot/Ankle:	Achilles tendon repair (4.9mm & 5.5mm only)

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™ SP Anchor
Date Prepared: 07/02/2020

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
Telephone: 508-828-3150
Email: emessan1@its.jnj.com

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

Name of Medical Device

Proprietary Name:
A) HEALIX ADVANCE™ SP PEEK Anchor
B) HEALIX ADVANCE™ SP BIOCOMPOSITE Anchor

Classification Name:
A) Smooth or threaded metallic bone fixation fastener
B) Single/multiple component metallic bone fixation appliances and accessories

Product Code:
A) MBI
B) MAI

Common Name:
Suture Anchor

Substantial Equivalence	The HEALIX ADVANCE SP PEEK Anchor is substantially equivalent to: • K182941, HEALIX ADVANCE SP PEEK Anchor The HEALIX ADVANCE SP BIOCOMPOSITE Anchor is substantially equivalent to: • K191242, HEALIX ADVANCE SP BIOCOMPOSITE Anchor
Device Classification	HEALIX ADVANCE SP PEEK Anchor is classified as: Fastener, Fixation, Nondegradable, Soft Tissue, classified as Class II, product code MBI, regulated under 21 CFR 888.3040. HEALIX ADVANCE SP BIOCOMPOSITE Anchor 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.
Device Panel	Orthopedic Devices
Device Description	The proposed HEALIX ADVANCE SP PEEK and BIOCOMPOSITE Anchors is a line extension to the currently marketed HEALIX ADVANCE SP Anchor family. Both versions of the device consist of a two-piece "self-punching" design consisting of a cannulated, threaded anchor (PEEK or BIOCOMPOSITE) and PEEK (Polyetheretherketone) dilator which are permanently implanted into the body. The anchor-dilator are preloaded on a disposable inserter shaft with handle, held in place by a non-absorbable stay suture comprised of Ultra-High Molecular Weight Polyethylene (UHMWPE) and Green poly (ethylene terephthalate) (PET). Following anchor-dilator implantation, the stay suture is discarded. The proposed HEALIX ADVANCE SP PEEK and BIOCOMPOSITE Anchors will be available in a new size option, 6.5 mm, molded from either Polyetheretherketone (PEEK) material or Absorbable Biocryl Biocomposite ((Polylactic Acid (PLA) and Tricalcium Phosphate (TCP)) material. Both the HEALIX ADVANCE SP PEEK Anchor and HEALIX ADVANCE SP BIOCOMPOSITE Anchor are provided sterile via Ethylene Oxide (EO) sterilization and are for single use only.

Technological Characteristics	The suture anchor design, principal of operation and indications for use are identical when compared to the predicate device- HEALIX ADVANCE™ SP PEEK Anchor (K182941). The suture anchor design and principal of operation are identical when compared to the predicate device- HEALIX ADVANCE™ SP BIOCOMPOSITE Anchor (K191242), and similar in terms of indications for use (a subset is pursued).
Indications for Use	The HEALIX ADVANCE SP PEEK Anchor is indicated for use in the following procedures for reattachment of soft tissue to bone: • Shoulder: Rotator cuff repair, biceps tenodesis, deltoid repair • Knee: Posterior oblique repair, medial collateral ligament (MCL) reconstruction, lateral collateral ligament reconstruction, iliotibial (IT) band tenodesis • Foot/Ankle: Achilles tendon repair The HEALIX ADVANCE SP BIOCOMPOSITE Anchor is indicated for use in the following procedures for reattachment of soft tissue to bone: • Shoulder: Rotator cuff repair, biceps tenodesis, deltoid repair • Knee: Posterior oblique repair, medial collateral ligament (MCL) reconstruction, lateral collateral ligament reconstruction, iliotibial (IT) band tenodesis • Foot/Ankle: Achilles tendon repair (4.9mm & 5.5mm only)
Non-clinical Testing	Verification activities were performed on the proposed device and its predicates. Performance testing included evaluation of *in-vitro* fixation strength at zero, six and twelve weeks, insertion torque, torque to failure and cyclic migration at time zero. 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 ADVANCE SP PEEK Anchor and HEALIX ADVANCE SP BIOCOMPOSITE Anchor has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.