Medos International SARL
% Ashley Goncalo
Senior Regulatory Affairs Specialist
DePuy Synthes Mitek Sports Medicine,
a Johnson and Johnson Company
325 Paramount Drive
Raynham, Massachusetts 02767

May 10, 2018

Re: K180101
Trade/Device Name: HEALIX ADVANCE™ KNOTLESS BR Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: April 9, 2018
Received: April 10, 2018

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

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)*
K180101

Device Name
HEALIX ADVANCE™ KNOTLESS BR Anchor

Indications for Use *(Describe)*
The HEALIX ADVANCE KNOTLESS BR Anchors are indicated for use in the following procedures for reattachment of soft tissue to bone:

Shoulder: Rotator Cuff, Biceps Tenodesis, Deltoid Repair
Knee: Posterior Oblique, Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), Iliotibial (IT) Band Tenodesis
Foot/Ankle: Achilles Tendon 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.

510(K) SUMMARY

HEALIX ADVANCE™ KNOTLESS BR Anchor

Date Prepared: 1/12/2018

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 Sr. Regulatory Affairs Specialist 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 KNOTLESS BR Anchor Classification Name: Single/multiple component metallic bone fixation appliances and accessories Common Name: Suture Anchor
Substantial Equivalence	The HEALIX ADVANCE KNOTLESS BR Anchor is substantially equivalent to: • K171114, K130917, K131974, K130539, K131683 HEALIX ADVANCE KNOTLESS Anchor • K101679, K082810, K071177, K061863, K051219 Arthrex PushLock Anchors
Device Classification	HEALIX ADVANCE KNOTLESS BR 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 Description	The HEALIX ADVANCE KNOTLESS BR Anchor is a one piece implantable cannulated, threaded anchor designed to secure soft tissue to bone. The anchor is provided loaded on a disposable inserter driver device. The proposed anchor is offered in three sizes, 4.75 mm, 5.5 mm and 6.5mm. The HEALIX ADVANCE KNOTLESS BR Anchors are molded from Biocryl Rapide® (BR) material. The HEALIX ADVANCE KNOTLESS BR Anchor is provided sterile and is for single use only.
Technological Characteristics	The suture anchor design, anchor and suture materials, and finished good assembly design remain the same when compared to the predicate HEALIX ADVANCE KNOTLESS Anchors (K171114, K130917, K131974, K130539, K131683).
Indications for Use	The HEALIX ADVANCE KNOTLESS BR Anchors are 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, Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), Iliotibial (IT) Band Tenodesis Foot/Ankle: Achilles Tendon Repair
Non-clinical Testing	Verification activities were performed on the proposed device and / or its predicates. Performance testing included evaluation of fixation strength and insertion torque at time zero as well as in-vitro testing. 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 KNOTLESS BR Anchor has shown

	to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act