October 6, 2023

Medos International SARL
℅ Elizabeth Messana
Senior Regulatory Specialist
DePuy Synthes Mitek Sports Medicine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K232492
Trade/Device Name: 2.7 mm GRYPHON™ Flex Knotless PEEK Anchor; 2.7 mm GRYPHON™ Flex Knotless 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: August 16, 2023
Received: August 17, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sara S. Thompson -S

For

Jesse Muir, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232492

Device Name
GRYPHON™ Flex Knotless Anchor

Indications for Use *(Describe)*
The GRYPHON™ Flex Knotless Anchor is indicated for use for reattachment of soft tissue to bone for the following procedures:

	Indication	PEEK	BIOCRYL
Shoulder	Bankart Repair	X	X
	SLAP Lesion Repair	X	X
	Capsular Shift or Capsulolabral Reconstruction	X	X
	Superior Capsule Reconstruction (Glenoid Only)	X	X
Hip	Acetabular Labral Repair	X	X
Knee	MCL	X	X
	LCL	X	X
	Iliotibial Band Tenodesis	X	X
Foot/Ankle	Lateral Stabilization	X	
	Medial Stabilization	X	

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
GRYPHON™ Flex Knotless Anchors
Date Prepared: 8/15/2023

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 P. Messana
Senior Regulatory Affairs Specialist
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) GRYPHON™ Flex Knotless PEEK Anchor
B) GRYPHON™ Flex Knotless 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 GRYPHON Flex Knotless PEEK and BIOCOMPOSITE Anchors are substantially equivalent to: • K101679, Arthrex PushLock Anchors (BIOCOMPOSITE) Reference Devices: • K182941 and K201883- HEALIX ADVANCE™ SP PEEK Anchor (MEDOS International), • K191242 and K201883 HEALIX ADVANCE™ SP BIOCOMPOSITE Anchor (MEDOS International), • K140643 GRYPHON™ Anchor W/ Proknot Technology (DePuy Mitek), • K040004 ORTHOCORD® Suture (DePuy Mitek), • K181182 DYNACORD™ Suture (MEDOS International).
Device Classification	GRYPHON Flex Knotless PEEK Anchor is classified as: Fastener, Fixation, Nondegradable, Soft Tissue, classified as Class II, product code MBI, regulated under 21 CFR 888.3040. GRYPHON Flex Knotless 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 GRYPHON Flex Knotless PEEK and BIOCOMPOSITE Anchors is a line extension to the currently marketed GRYPHON Anchor family. The proposed product is a knotless anchor intended for fixation of soft tissue to bone in various soft tissue repair procedures. In its finished good configuration, the proposed device is a two-piece design; comprised of a permanent implant (anchor) component and a disposable (inserter) component. The 2.7mm anchor implant is preloaded on the inserter and a Nitinol distal tip retains the suture and the anchor while the device is malleted into the bone. The design offers surgeons maneuverability within the joint space. The disposable inserter will be offered in two design configurations, straight or curved to accommodate varying anatomies. The proposed GRYPHON Flex Knotless PEEK and BIOCOMPOSITE Anchors will be available in a 2.7 mm size, molded from either Polyetheretherketone (PEEK) material or

	Absorbable Biocryl Biocomposite ((Polylactic Acid (PLA) and Tricalcium Phosphate (TCP)) material. Both the GRYPHON Flex Knotless PEEK and BIOCOMPOSITE Anchors 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 similar when compared to the predicate device- Arthrex PushLock **(**BIOCOMPOSITE**)** Anchors**,** (K101679). A subset of indications will be pursued for the proposed device. The PEEK material of the proposed device is identical to that present in the reference device- K182941 and K201883- HEALIX ADVANCE**™** SP PEEK Anchor. The Biocomposite material of the proposed device is identical to that present in the reference device- K191242 and K201883- HEALIX ADVANCE™ SP BIOCOMPOSITE Anchor
Indications for Use	The GRYPHON™ Flex Knotless Anchor is indicated for use for reattachment of soft tissue to bone for the following procedures:

	Indication	PEEK	BIOCRYL
Shoulder	Bankart Repair	X	X
	SLAP Lesion Repair	X	X
	Capsular Shift or Capsulolabral Reconstruction	X	X
	Superior Capsule Reconstruction (Glenoid Only)	X	X
Hip	Acetabular Labral Repair	X	X
Knee	MCL	X	X
	LCL	X	X
	Iliotibial Band Tenodesis	X	X
Foot/Ankle	Lateral Stabilization	X	
	Medial Stabilization	X	

Non-clinical Testing	Verification activities were performed on the proposed device and its predicate. Non-clinical performance testing included evaluation of *in-vitro* fixation strength at zero, six, twelve, thirteen and twenty-six weeks, insertion torque, torque to failure and cyclic & post cyclic fixation at time zero.

	Ethylene Oxide Sterilization was validated according to ANSI/AAMI/ISO 11135: 2014 to a SAL of 1 x 10^{-6}. EO residuals were tested per AAMI/ANSI/ISO 10993-7:2008. Biological safety was evaluated according to ISO 10993-1 for devices having direct patient contact, inclusive of raw materials of components, manufacturing processes, sterilization, and primary packaging materials. 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 non-clinical 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 testing in comparison to the predicate devices, the proposed GRYPHON Flex Knotless PEEK and BIOCOMPOSITE Anchors have demonstrated that they are substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.