August 3, 2018

Medos International SARL
℅ Tatyana Korsunsky
Regulatory Affairs Technical Manager
DePuy Mitek, a Johnson & Johnson company
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K181809
Trade/Device Name: GRYPHON® Anchors with DYNACORD™ Suture
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: July 3, 2018
Received: July 6, 2018

Dear Ms. Korsunsky:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Sarah B. Nelson -S

For 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)*
K181809

Device Name
GRYPHON® Anchors with DYNACORD™ Suture

Indications for Use *(Describe)*
The GRYPHON® BR Anchor with DYNACORD™ Suture is intended for:

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 or Radial Collateral Ligament Reconstruction
Hip:	Capsular Repair, Acetabular Labral Repair

The GRYPHON® PEEK Anchor with DYNACORD™ Suture is intended for:

Shoulder:	Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Foot/Ankle:	Lateral Stabilization, Medial Stabilization
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Elbow:	Ulnar or 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

GRYPHON® Anchors with DYNACORD™ Suture

510k Document Number: K181809

Date Prepared: July 30th, 2018

Submitter's Name and Address

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Contact Person

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Name of Medical Device

Proprietary Name: GRYPHON® Anchor with DYNACORD™ Suture:
a) GRYPHON® BR Anchor with DYNACORD™ Suture
b) GRYPHON® PEEK Anchor with DYNACORD™ Suture

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 GRYPHON® Anchors with DYNACORD™ Suture are substantially equivalent to:

- K141259 GRYPHON® Anchors with PERMACORD™ Suture

Reference devices:

- K173859 HEALIX ADVANCE™ Anchors with DYNACORD™ Suture

Device Classification

- GRYPHON® BR Anchor with DYNACORD™ Suture 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.

- GRYPHON® PEEK Anchor with DYNACORD™ 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 Description	The GRYPHON® Anchor with DYNACORD™ Suture is a push-in suture anchor preloaded on a disposable inserter assembly intended for fixation of soft tissue to bone. The GRYPHON® Anchors with DYNACORD™ Suture are available in absorbable BR and non-absorbable PEEK materials. The GRYPHON® Anchors with DYNACORD™ is provided sterile and is for single use only.
Technological Characteristics	The proposed GRYPHON® Anchors with DYNACORD™ Suture has the same anchor materials, design, principle of operation, as well as device assembly, sterilization method, and shelf life, as predicate GRYPHON® Anchors with PERMACORD™ Suture (K141259). The DYNACORD™ Suture component is a non-absorbable suture that conforms to USP, except for oversized diameter. The DYNACORD™ Suture is designed to resist laxity and minimize gap formation, by maintaining approximation force (compression). DYNACORD™ Suture on the GRYPHON® Anchors is the same as the DYNACORD™ Suture on reference predicate HEALIX ADVANCE™ Anchors with DYNACORD™ Suture (K173859).
Indications for Use	GRYPHON® BR Anchors with DYNACORD™ Suture are indicated for: **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 or Radial Collateral Ligament Reconstruction **Hip:** Capsular Repair, Acetabular Labral Repair GRYPHON® PEEK Anchors with DYNACORD™ Suture are indicated for: **Shoulder:** Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction **Foot/Ankle:** Lateral Stabilization, Medial Stabilization **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis **Elbow:** Ulnar or Radial Collateral Ligament Reconstruction **Hip:** Capsular Repair, Acetabular Labral Repair.

Non clinical Testing	Non-clinical testing has been performed on the proposed device and / or its predicates. Performance testing included anchor fixation testing and *in-vitro* testing. Safety evaluations were conducted to address sterility, packaging, shelf-life testing. Bacterial endotoxin testing has been completed on representative device and results have demonstrated that the proposed devices meet the endotoxin limits.
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 GRYPHON® Anchors with DYNACORD™ Suture has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.