August 2, 2018

Medos International SARL
DePuy Mitek, a Johnson and Johnson company
% Ms. Tatyana Korsunsky
Regulatory Affairs Technical Manager
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K181182
Trade/Device Name: DYNACORD™ Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: July 3, 2018
Received: July 5, 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*

K181182

Device Name
DYNACORD™ Suture

Indications for Use *(Describe)*
DYNACORD suture is indicated for orthopedic procedural use in soft-tissue approximation, and/or ligation, including use with allograft tissue.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

DYNACORD™ Suture

Date Prepared: June 27, 2018

Submitter's Name and Address

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

Contact Person

Tatyana Korsunsky
Regulatory Affairs Technical Manager
DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767, USA

Telephone: 508-828-3122
e-mail: tkorsuns@its.jnj.com

Name of Medical Device

Proprietary Name: DYNACORD™ Suture

Classification Name: Polyethylene, suture, nonabsorbable, synthetic (21 CFR 878.5000)

Common Name: Suture

Substantial Equivalence

The DYNACORD™ Suture is substantially equivalent to:

- K021434, K041553 FiberWire® (Arthrex)

Reference devices:

- K173859 HEALIX ADVANCE™ Anchor with DYNACORD™ Suture (MEDOS International)
- K040004 ORTHOCORD® Suture (DePuy Mitek)

Device Classification

DYNACORD™ Suture is classified as:

Polyethylene, suture, nonabsorbable, synthetic, classified as Class II, product code GAT, regulated under 21 CFR 878.5000.

Device Description

DYNACORD™ Suture is a sterile non-absorbable orthopedic suture. DYNACORD™ Suture has a double sheath and core design, and contains Ultra High Molecular Weight Polyethylene, Polyester and a Silicone/NaCl core.

Technological Characteristics	The DYNACORD™ Suture is a surgical suture, that meets USP except for oversized diameter. When DYNACORD™ Suture is placed in an aqueous environment, the salt particles within the silicone core elute out, leaving behind a micro-porous structure within the silicone core. These small voids are consequently filled with surrounding fluid as the core hydrates, resulting in a radial expansion of the suture. If laxity is present, this radial expansion of the braid causes an axial shortening of the total suture length. The DYNACORD™ Suture is designed to resist laxity and minimize gap formation, by maintaining approximation force (compression).
Comparison to the Predicate Devices	The DYNACORD™ Suture, similar to the predicate device FiberWire® (Arthrex, K021434, K041553), meets USP requirements for size 2 suture, except for oversized diameter. Both subject and predicate device have the same intended use of soft tissue approximation. Both sutures contain UHMWPE and Polyester. FiberWire® (Arthrex) contains Silicone coating. DYNACORD™ Suture contains Silicone/NaCl core. The silicone/NaCl core is the main technological difference between the DYNACORD™ Suture and FiberWire® (Arthrex) Suture. The DYNACORD™ Suture is identical to the suture component of the reference predicate HEALIX ADVANCE™ Anchors with DYNACORD™ Suture (K173859). The needles provided with DYNACORD™ Suture are also used with reference predicate device ORTHOCORD®(K040004).
Indications for Use	DYNACORD™ suture is indicated for orthopedic procedural use in soft-tissue approximation, and/or ligation, including use with allograft tissue.
Non clinical Testing	Performance testing included: USP Diameter (DYNACORD™ is oversized), USP Knot Tensile Strength, USP Needle Attachment, *in-vitro* approximation force over time, GLP *in-vivo* efficacy evaluation. Safety testing included: biocompatibility, sterility, shelf-life, GLP *in-vivo* evaluation of DYNACORD™ safety. Bacterial endotoxin testing has been completed and results have demonstrated that the proposed devices meet the endotoxin limits.
Safety and Performance	Results of non-clinical 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 device, the proposed DYNACORD™ Suture has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.