March 18, 2021

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

Re: K203186
Trade/Device Name: DYNATAPE Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: October 25, 2020
Received: October 27, 2020

Dear Tatyana 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/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,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K203186

Device Name
DYNATAPE™ Suture

Indications for Use *(Describe)*
DYNATAPE 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.

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510(k) SUMMARY

DYNATAPE™ Suture

Date Prepared: February 09, 2021

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

Tatyana Korsunsky
Regulatory Affairs Technical Manager
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DePuy Synthes Mitek Sports Medicine
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

Name of Medical Device

Proprietary Name:	DYNATAPE™ Suture
Classification Name:	Polyethylene, suture, nonabsorbable, synthetic (21 CFR 878.5000)
Common Name:	Suture

Substantial Equivalence

The DYNATAPE™ Suture is substantially equivalent to:

- K181182 DYNACORD™ Suture (MEDOS International SARL)

Reference devices:

- K200949 HEALIX ADVANCE™ Anchor with DYNATAPE™ Suture (MEDOS International SARL)
- K183506 HEALIX ADVANCE™ Anchor with DYNACORD™ Suture (MEDOS International SARL)
- K021434, K041553 FiberWire® (Arthrex)

Device Classification	DYNATAPE™ Suture is classified as: Polyethylene, suture, nonabsorbable, synthetic, classified as Class II, product code GAT, regulated under 21 CFR 878.5000.
Device Description	DYNATAPE™ Suture is a sterile non-absorbable orthopedic suture. DYNATAPE™ Suture has a double sheath and core design, composed of Ultra High Molecular Weight Polyethylene and Polyester, with or without colorants, as well as a Silicone/NaCl core. DYNATAPE™ Suture's outer sheath is braided flat, with rounded tips.
Technological Characteristics	The DYNATAPE™ Suture is a surgical suture, that meets USP knot tensile strength for size 2 non-absorbable sutures. As DYNATAPE™ Suture is flat, it does not follow USP suture diameter requirements. DYNATAPE™ Suture's outer sheath is braided flat to allow for a wider contact area with tissue. When DYNATAPE™ 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 self-tensioning property of DYNATAPE™ Suture is designed to resist laxity and minimize gap formation in a repair, by maintaining approximation force (compression) if laxity (looseness) is present.
Comparison to the Predicate Devices	The DYNATAPE™ Suture, similar to the predicate device DYNACORD® (K181182), meets USP knot tensile requirements for size 2 suture. Both subject and predicate device have the same indications, intended use and materials. Both DYNATAPE™ and DYNACORE™ sutures are laxity resistant, as shown by approximation force testing. The sheath of the DYNATAPE™ Suture has been redesigned with a unique braiding pattern of ticker fibers to create the flattened structure specific to DYNATAPE™ Suture, differentiating from the predicate device. DYNATAPE™ Suture is offered as a suture component of the reference predicate HEALIX ADVANCE™ Anchor with DYNATAPE™ Suture (K200949).
Indications for Use	DYNATAPE suture is indicated for orthopedic procedural use in soft-tissue approximation, and/ or ligation, including use with allograft tissue.
Non clinical Testing	USP Knot Tensile Strength, *in-vitro* approximation force over time, and sterility testing have been conducted. Biocompatibility, stability, in-vivo testing of the predicate device were included by reference (K181182). Bacterial endotoxin testing

	has been completed as part of the HEALIX ADVANCE™ Anchor with DYNATAPE™ Suture (K200949), meeting 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 DYNATAPE™ Suture has shown to be substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.