April 26, 2022

Medos International SARL
% Ashley Aromando (Goncalo)
Regulatory Affairs Project Manager
DePuy Synthes Mitek Sports Medicine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K220219
Trade/Device Name: PERMALOOP Suture, PERMATAPE Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: January 20, 2022
Received: January 26, 2022

Dear Ashley Aromando (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. 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,

for Deborah Fellhauer, RN, BSN
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)*

K220219

Device Name
PERMALOOP™ Suture

Indications for Use *(Describe)*
The PERMALOOP Suture is indicated for orthopedic procedural use in soft-tissue approximation 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."

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)*

K220219

Device Name
PERMATAPE™ Suture

Indications for Use *(Describe)*
The PERMATAPE Suture is indicated for orthopedic procedural use in soft-tissue approximation 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)

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510(K) SUMMARY

PERMATAPE™ 1.3mm Suture, PERMALOOP™ Suture
Date Prepared: 1/21/22

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 Aromando
Project Manager, Regulatory Affairs

Telephone: 508-977-3907
Email: aaromand@its.jnj.com

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

Name of Medical Device

Proprietary Name: PERMATAPE™ Suture, PERMALOOP™ Suture
Classification Name: 21 CFR 878.5000 Nonabsorbable polyethylene surgical suture
Product Code: GAT
Common Name: Suture

Substantial Equivalence

The PERMATAPE™ Suture and PERMALOOP™ Suture are substantially equivalent to:

- K162247 PERMATAPE Suture

Reference Device:

- K122374 Arthrex Fiberloop Suture

Device Classification

The PERMATAPE™ Suture and PERMALOOP™ Suture are classified as:

	Nonabsorbable polyethylene surgical suture, classified as Class II, product code GAT, regulated under 21 CFR 878.5000.
Device Panel	General & Plastic Surgery
Device Description	The PERMATAPE™ Suture is a 1.3mm wide, synthetic, sterile, flat braided suture composed of dyed and un-dyed (chromium cobalt aluminum oxide <2.0%, 21 CFR 73.1015), non-absorbable polyethylene. The PERMATAPE Sutures are provided with and without stainless steel needles. The PERMALOOP™ Suture is a suture loop constructed from the proposed PERMATAPE 1.3mm Suture. The PERMALOOP Sutures are offered with a curved, stainless steel needle attachment configuration or a straight, stainless steel needle attachment configuration. Both the PERMATAPE Suture and PERMALOOP suture are sterile via Ethylene Oxide (EO) sterilization and are for single use only. The devices are provided packaged in a pack of twelve (12).
Technological Characteristics	The design, principal of operation and intended use of the proposed sutures are nearly identical to that of the predicate PERMATAPE Suture (K162247). Furthermore, the material of the proposed sutures is identical to polyethylene material of the predicate PERMATAPE Suture. The looped design feature of the PERMALOOP Suture is a technological characteristic which is found in other general orthopedic surgical sutures, such as the reference device, Arthrex Fiberloop Suture (K122374). Any differences between the proposed device and the predicate are considered non-significant and do not raise different questions of safety or effectiveness.
Indications for Use	The PERMATAPE Suture is indicated for orthopedic procedural use in soft-tissue approximation including use with allograft tissue. The PERMALOOP Suture is indicated for orthopedic procedural use in soft-tissue approximation including use with allograft tissue.
Non-clinical Testing	PERMATAPE Suture and PERMALOOP Suture performance was tested per USP Tensile Strength and Needle Attachment Strength for Surgical Sutures and follows FDA's Special Controls Guidance

	document for Surgical Sutures. Identical to the predicate, it does not conform to USP Diameter and size classification due to its flat braiding. Ethylene Oxide Sterilization was validated according to ANSI/AAMI/ISO 11135: 2014 to a SAL of 1×10^{-6}. EO residuals were tested per AAMI/ANSI/ISO 10993-7:2008 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 intended use, technological characteristics, and performance in comparison to the predicate devices, the proposed PERMATAPE Suture and PERMALOOP Suture have shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.