DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 15, 2016

Medos International Sarl
% Ms. Tatyana Korsunsky
Depuy Mitek, A Johnson And Johnson Company
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K162247
Trade/Device Name: Permatape
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: November 14, 2016
Received: November 15, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162247

Device Name
PERMATAPE™

Indications for Use *(Describe)*
PERMATAPE Suture is indicated for use in general soft tissue approximation, and/or ligation, including use with allograft tissue for orthopedic procedures.

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
PERMATAPE™ SUTURE

Date Prepared: 08/08/2016

Submitter's Name and Address	Medos International SARL Chemin-Blanc 38, Le Locle Neuchatel CH 2400, Switzerland

Contact Person	Tatyana Korsunsky Regulatory Affairs Project Lead DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-828-3122 Facsimile: 508-977-6911 e-mail: tkorsuns@its.jnj.com

Name of Medical Device	Proprietary Name: PERMATAPE™ SUTURE Classification Name: Polyethylene, suture, nonabsorbable, synthetic (21 CFR 878.5000) Common Name: Suture

Substantial Equivalence Predicate Devices	The PERMATAPE™ SUTURE is substantially equivalent to: ▪ K040004: ORTHOCORD® Suture (DePuy Mitek) Reference Devices: ▪ K130814: RIGIDLOOP™ Cortical Fixation system (DePuy Mitek) ▪ K141259: Gryphon™ Anchor with Permacord™ (DePuy Mitek) ▪ K150438: Smith & Nephew ULTRATAPE (Smith & Nephew)

Device Description	PERMATAPE™ Suture is a synthetic, sterile, flat braided suture composed of dyed and un-dyed, non-absorbable polyethylene.

Indications for Use	PERMATAPE™ Suture is indicated for use in general soft tissue approximation, and/or ligation, including use with allograft tissue for orthopedic procedures.

Technological Characteristics and Performance	The proposed PERMATAPE™ is a non-absorbable surgical suture. The determination of substantial equivalence for this device was based on a detailed device description, performance data, and conformance to consensus and voluntary standards. PERMATAPE™ Suture is similar in intended use, materials, sterilization method to the

predicate DePuy Mitek's ORTHOCORD® (K040004) suture. Its polyethylene material is also comparable to reference predicates DePuy Mitek's RIGIDLOOP™ Cortical Fixation system (K130814) and Gryphon™ Anchor with Permacord™ (K141259). PERMATAPE™ is a flat type of suture, similar to reference predicate Smith & Nephew's ULTRATAPE (K150438).

PERMATAPE™ Suture's performance was tested per USP Tensile Strength for Surgical Sutures and follows FDA's Special Controls Guidance document for Surgical Sutures, however, it does not conform to USP Diameter and size classification due to its flat braiding. The proposed device met requirement of bacterial endotoxin testing.

Based on the similarities of the intended use, materials, technological characteristics and USP Tensile testing, the PERMATAPE™ suture has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.