July 25, 2019

Medos International SARL
% LeeAnn Walosin
Regulatory Affairs Specialist
DePuy Mitek, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K190774
Trade/Device Name: RIGIDLOOP™ Titanium Button, RIGIDLOOP™ Cortical Fixation System XL Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 27, 2019
Received: June 28, 2019

Dear LeeAnn Walosin:

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,

Laurence D. Coyne, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190774

Device Name
RIGIDLOOP™ Titanium Button
RIGIDLOOP™ Cortical Fixation System XL Implant

Indications for Use *(Describe)*
The RIGIDLOOP Titanium Button is intended for fixation of soft-tissue to bone for the following indications when used with PERMATAPE™ 2.5mm Suture, #2 ORTHOCORD® Suture, #2 DYNACORD™ Suture, or equivalent nonabsorbable or partially-absorbable high strength operative suture:

Shoulder:
Acromioclavicular repair
Pectoralis major / minor repair(1)
Biceps tenodesis

Elbow:
Ulnar or radial collateral ligament reconstruction
Biceps tendon reattachment

Knee:
Cruciate ligament reconstruction (1)
Extracapsular repair: MCL, LCL, and Posterior oblique ligament
Patellar tendon repair
Meniscal root repair(2)

(1) PERMATAPE 2.5mm suture must be used for pectoralis major/minor repair and cruciate ligament reconstruction
(2) Size 0 or size 2/0 ORTHOCORD Suture may be used for meniscal root repair.

RIGIDLOOP™ Cortical Fixation System XL Implant

When used in conjunction with the RIGIDLOOP Cortical Fixation System, the RIGIDLOOP Cortical Fixation System XL Implant is intended for fixation of soft tissue to bone in orthopaedic procedures such as ACL repairs.

When used in conjunction with the RIGIDLOOP Titanium Button, the RIGIDLOOP Cortical Fixation System XL Implant is intended for fixation of soft-tissue to bone for the following indications:

Shoulder:
Pectoralis major / minor repair
Biceps tenodesis

Elbow:
Ulnar or radial collateral ligament reconstruction
Biceps tendon reattachment

Knee:
Cruciate ligament reconstruction
Extracapsular repair: MCL, LCL, and Posterior oblique ligament
Patellar tendon repair
Meniscal root 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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DePuy Synthes
MITEK SPORTS MEDICINE
COMPANIES OF Johnson & Johnson

510(k) SUMMARY

RIGIDLOOP Titanium Button & RIGIDLOOP XL Implant

Date Summary Prepared	March 25, 2019	
Submitter's Name and Address	DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767	
Legal Manufacturer	Medos International SARL Chemin-Blanc 38, Case Postale CH 2400 Le Locle, Switzerland	
Contact Person	LeeAnn Walosin Regulatory Affairs Specialist DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA	Telephone: 612-230-9909 Facsimile: 508-977-6409 e-mail: lswiftwa@its.jnj.com
Name of Medical Device	Proprietary Name: Common Name:	RIGIDLOOP™ Titanium Button; RIGIDLOOP™ Cortical Fixation System XL Implant Fixation Device
Device Classification	Smooth or threaded metallic bone fixation fastener, classified as Class II, product code MBI regulated per 21 CFR 888.3040. (Orthopedic panel)	

Substantial Equivalence	The proposed RIGIDLOOP Titanium Button and the RIGIDLOOP Cortical Fixation System XL Implant (when used with the proposed RIGIDLOOP Titanium Button) are substantially equivalent to the following predicate devices: **PREDICATE DEVICES:** • **ARTHREX PEC REPAIR BUTTON, LARGE PEC BUTTON, BICEP BUTTON, PROXIMAL BICEPS BUTTON, (**Arthrex: K123341) • **SWIVELOCK** (Arthrex: K173845) **REFERENCE DEVICE:** • **RIGIDLOOP CORTICAL FIXATION SYSTEM**, (Depuy Mitek *a Johnson & Johnson Company*: K130814)
Indications for Use	**RIGIDLOOP Titanium Button** The RIGIDLOOP Titanium Button is intended for fixation of soft-tissue to bone for the following indications when used with PERMATAPE™ 2.5mm Suture, #2 ORTHOCORD® Suture, #2 DYNACORD™ Suture, or equivalent nonabsorbable or partially-absorbable high strength operative suture: **Shoulder:** Acromioclavicular repair Pectoralis major / minor repair[1] Biceps tenodesis **Elbow:** Ulnar or radial collateral ligament reconstruction Biceps tendon reattachment **Knee:** Cruciate ligament reconstruction [1] Extracapsular repair: MCL, LCL, and Posterior oblique ligament Patellar tendon repair Meniscal root repair[2] [1] PERMATAPE 2.5mm suture must be used for pectoralis major/minor repair and cruciate ligament reconstruction [2] Size 0 or size 2/0 ORTHOCORD Suture may be used for meniscal root repair.

	RIGIDLOOP Cortical Fixation System XL Implant When used in conjunction with the RIGIDLOOP Cortical Fixation System, the RIGIDLOOP Cortical Fixation System XL Implant is intended for fixation of soft tissue to bone in orthopedic procedures such as ACL repairs. When used in conjunction with the RIGIDLOOP Titanium Button, the RIGIDLOOP Cortical Fixation System XL Implant is intended for fixation of soft-tissue to bone for the following indications: **Shoulder:** Pectoralis major / minor repair Biceps tenodesis **Elbow:** Ulnar or radial collateral ligament reconstruction Biceps tendon reattachment **Knee:** Cruciate ligament reconstruction Extracapsular repair: MCL, LCL, and Posterior oblique ligament Patellar tendon repair Meniscal root repair
Device Description	**RIGIDLOOP Titanium Button** The proposed RIGIDLOOP Titanium Button is a cortical fixation device that provides a means of fixation of soft tissue to bone in orthopedic reconstructive surgery. The device consists of a titanium button implant that is provided with pre-attached leading and trailing sutures that are non-implantable. The white leading utility suture is composed of UHMWPE (device high molecular weight polyethylene) and the green trailing suture is composed of #5 Ethibond®. This device is provided sterile and is for single use only. **RIGIDLOOP Cortical Fixation System XL Implant** The RIGIDLOOP XL Implant is an extra-large titanium button implant that is currently intended for use with the already cleared RIGIDLOOP Cortical Fixation System devices (K130814). The RIGIDLOOP XL Implant can now also be used with the proposed RIGIDLOOP Titanium Button for the proposed indications. The RIGIDLOOP XL Implant is used in cases of cortical breaching. This device is provided sterile and is for single use only.
Technological Characteristics	The proposed device, the RIGIDLOOP Titanium button (when used as a standalone system and when used in conjunction with the currently marketed RIGIDLOOP Cortical Fixation System XL Implant),

	has the same intended use and indications as the predicate devices. Although there are differences between the proposed device and the predicate in the implant design, implant size, implant material, operative sutures, and principle in operation, performance testing has demonstrated that the proposed device is as safe and effective as the predicates and that the differences do not raise any different questions concerning safety and efficacy. Based on this comparison with the predicate devices, the proposed device is considered substantially equivalent to the predicate devices: ARTHREX PEC REPAIR BUTTON, LARGE PEC BUTTON, BICEP BUTTON, PROXIMAL BICEPS BUTTON, (Arthrex: K123341) and SWIVELOCK (Arthrex: K173845). The implant design, implant materials, and implant materials are identical to the reference device; the principle of operation is similar when compared to the reference device: RIGIDLOOP CORTICAL FIXATION SYSTEM, (Depuy Mitek a Johnson & Johnson Company: K130814).
Non-clinical Testing	Verification activities have been performed on the proposed RIGIDLOOP Titanium button, when used as a standalone device, when used in conjunction with the currently marketed RIGIDLOOP Cortical Fixation System XL Implant, and also on the chosen predicates. Performance testing included an evaluation of fixation strength. The testing demonstrated substantial equivalence of device performance. Safety evaluations were conducted to address biological, sterility, packaging and shelf-life testing. Bacterial Endotoxin Testing has been completed and results have demonstrated that the proposed devices meet the endotoxin limits. No animal or clinical studies were required. The proposed device has raised no new issues of safety and efficacy.
Safety and Performance	Results of the 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 device is considered substantially equivalent to the predicate devices.