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MITEK SPORTS MEDICINE
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510(k) SUMMARY
RIGIDLOOP™ Adjustable Cortical Fixation System

Date Summary Prepared	February 7, 2014	
Submitter's Name and Address	Medos International SARL Chemin-Blanc 38, Case Postale CH 2400 Le Locle, Switzerland	
Contact Person	Yayoi Fujimaki Regulatory Affairs Senior Associate DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA	Telephone: 508-828-3541 Facsimile: 508-977-6911 e-mail: yfujima1@its.jnj.com
Name of Medical Device	Trade Name: RIGIDLOOP™ Adjustable Cortical Fixation System Common Name: Fastener, fixation, nondegradable, soft tissue	
Device Classification	▪ MBI - Smooth or threaded metallic bone fixation fastener, classified as Class II, regulated per 21 CFR 888.3040. ▪ Orthopedic panel	
Predicate Device	▪ ToggleLoc System with ZipLoop Technology (K083070, K130033; Biomet Sports Medicine) ▪ Milagro Advance Interference Screw (K123362, DePuy Mitek)	
Indications for Use	The RIGIDLOOP Adjustable Cortical Fixation System is indicated for fixation of soft tissue to bone in Femoral Cruciate Ligament Reconstruction.	
Device Description	The proposed device is a cortical fixation system composed of titanium button, adjustable suture (Ultra-high molecular polyethylene (UHMWPE)), leading suture (UHMWPE and green Polyester (PET) co-braid) and training suture (green PET). Length of the suture loops is adjustable to the desired length. The proposed device provides a fixation in cruciate ligament reconstructive surgery. The device is provided as sterile for single patient use only.	

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Safety and Performance	**Non-clinical Testing** Fixation strength testing (bench-top) was conducted. The testing demonstrated substantial equivalence of device performance. The proposed device has been determined biocompatible for the intended use based on biocompatibility data. The proposed device has raised no new issue of safety and efficacy.
Substantial Equivalence	The predicate devices have been used for the proposed indications. The proposed device is a cortical fixation device that consists of a titanium button and non-absorbable sutures. Technological characteristics and fixation strength are substantially equivalent to the predicate devices. Differences found between the proposed and the predicate devices are considered minor and do not raise questions concerning safety and efficacy. Based on the indications for use, technological characteristics and comparison with the predicate devices, we determined that the proposed device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 7, 2014

Medos International Sárl
% Ms. Yayoi Fujimaki
DePuy Mitek, *a Johnson & Johnson company*
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K140324
Trade/Device Name: RIGIDLOOP™ Adjustable Cortical Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 4, 2014
Received: June 5, 2014

Dear Ms. Fujimaki:

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 yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic 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 on last page.

510(k) Number *(if known)*
K140324

Device Name
RIGIDLOOP™ Adjustable Cortical Fixation System

Indications for Use *(Describe)*

The RIGIDLOOP Adjustable Cortical Fixation System is indicated for fixation of soft tissue to bone in Femoral Cruciate Ligament Reconstruction.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

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