SECTION 2 - 510(k) SUMMARY

RIGIDLOOP Cortical Fixation System

Recognized Manufacturer:	Medos International SarL Puits Godet 20 CH 2000 Neuchâtel Switzerland
Submitter:	DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767
	Date Prepared: April 17, 2013

AUG 1 2013

Contact Person	Kristine Christo Manager, Regulatory Affairs DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA	Telephone: 508-828-3359 Facsimile: 508-977-6911 e-mail: KChristo@its.jnj.com

Name of Medical Device	Proprietary Name:	RIGIDLOOP Cortical Fixation System
	Classification Name:	Fastener, Fixation, Nondegradable, Soft tissue
	Common Name:	Fastener, Fixation, Soft Tissue

Substantial Equivalence

The RIGIDLOOP Cortical Fixation Systemis substantially equivalent to:

- K980155 Smith & Nephew EndoButton Continuous Loop
- K081098 Smith & Nephew EndoButton Continuous Loop
- K060664 Fastin RC Anchors
- K040004 / K042398 Orthocord suture

Device Classification

Smooth or threaded metallic bone fixation fastener, classified as Class II, product code MBI regulated under 21 CFR 888.3040.

Device Description	The RIGIDLOOP Cortical Fixation System is a machined titanium implant designed to provide fixation in the repair of tendons and ligaments. It consists of a titanium implantable button with a pre-attached non-absorbable fiber loop. This implantable fiber loop has non-absorbable suture attached to the button for assisting in the button placement and is discarded after the device placement. The device is offered in size ranges of 15-60mm in 5mm increments. Reamers and depth gauges are provided separately as reusable accessories to assist in the placement of the RIGIDLOOP Cortical Fixation System.
Technological Characteristics	The proposed RigidLoop Fixation Device consists of similar materials and design as predicate Smith &Nephew Endobutton Cl (K980155, K081098). The proposed device principal operation is identical to predicate Smith &Nephew Endobutton CL (K980155, K081098). The RigidLoop Cortical Fixation Device has no new technological characteristics as compared to the predicate Smith &Nephew Endobutton CL (K980155, K081098).
Indications for Use	The RIGIDLOOP™ Cortical Fixation System is used for the fixation of soft tissue to bone in orthopedic procedures such as ACL repair.
Non clinical Testing	Verification activities were performed on the implant and / or its predicates. Testing assessments include pull out testing, shelf-life, sterilization and biocompatibility.
Safety and Performance	Results of performance testing have demonstrated that the proposed devices are suitable for their intended use. Based on the indications for use, technological characteristics, and comparison to the predicate devices, the proposed RIGIDLOOP Cortical Fixation System has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

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

August 1, 2013

DePuy Mitek, Incorporated
% Ms. Kristine Christo
Manager, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K130814
Trade/Device Name: RigidLoop 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 27, 2013
Received: July 2, 2013

Dear Ms. Christo:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130814

Device Name: RigidLoop Cortical Fixation System

Indications for Use:

The RIGIDLOOP™ Cortical Fixation System is used for the fixation of soft tissue to bone in orthopedic procedures such as ACL repair.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices