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

Medos International SARL
% Yayoi Fujimaki
Regulatory Affairs Senior Associate
Depuy Mitek, a Johnson & Johnson Company
325 Paramount Drive
Raynham, Massachusetts 02767

March 24, 2016

Re: K153667
Trade/Device Name: TRUESPAN™ Meniscal Repair System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 17, 2016
Received: February 18, 2016

Dear Yayoi 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 Parts 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" (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 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,

Mark N. Melkerson -S

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)*

K153667

Device Name
Truespan Meniscal Repair System

Indications for Use *(Describe)*
The TRUESPAN Meniscal Repair System is intended for use in meniscal repairs and meniscal allograft transplant procedures. The TRUESPAN Meniscal Repair System is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant 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)

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DePuy Synthes
MITEK SPORTS MEDICINE
COMPANIES OF Johnson & Johnson

510(k) SUMMARY
TRUESPAN™ Meniscal Repair System

Date Summary Prepared	December 18, 2015	
Submitter's Name and Address	DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767	
Manufacturer	Medos International SARL Chemin-Blanc 38, Le Locle Neuchatel CH 2400, 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: TRUESPAN™ Meniscal Repair System Common Name: Fastener, fixation, degradable, 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	▪ Predicate: Fast-Fix 360 Meniscal Repair System (K121861, K092508; Smith & Nephew) ▪ Reference: Ultra Fast-Fix Meniscal Repair System (K121861, K072322; Smith & Nephew) ▪ Reference: Omnispan Meniscal Repair System (K092836, DePuy Mitek)	
Indications for Use	The TRUESPAN Meniscal Repair System is intended for use in meniscal repairs and meniscal allograft transplant procedures. The TRUESPAN Meniscal Repair System is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.	
Device Description	The proposed device is an all-inside meniscal repair system. The implant consists of two rigid backstops (absorbable PLGA[*1] or non-absorbable PEEK[*2]), size #2-0 Orthocord suture and UHMWPE braid. The implant system and applier are pre-assembled, and the whole device is sterile, for single patient use only. Compression of the fixation point is accomplished by pulling on the suture post to allow the two suture strands creating the bridge between the implants to	

	lay tight on the surface of the fixation point. *1 PLGA: Poly(lactide-co-glycolide) *2 PEEK: polyaryletherketone
Safety and Performance	Implant system strength was evaluated *in vitro* and after cyclic (bench top). The testing demonstrated substantial equivalence of performance to the predicate device. Biocompatibility is also confirmed based on biocompatibility data and justification. The proposed device has raised no new issue of safety and efficacy.
Substantial Equivalence	The proposed device is an all-inside meniscal repair system. The proposed device consists of two rigid backstops and sutures. The technological characteristics are similar to the predicate device. Implant system strength demonstrated substantial equivalency of performance. Differences found between the proposed and the predicate device are considered minor and do not raise questions concerning safety and efficacy. The proposed device is determined substantially equivalent to the predicate device.