January 18, 2018

Medos International SARL
% Tatyana Korsunsky
Regulatory Affairs Project Lead
DePuy Mitek, a Johnson and Johnson Company
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K171237
Trade/Device Name: FMS VUE II Fluid Management and Tissue Debridement System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: November 12, 2017
Received: December 14, 2017

Dear Tatyana 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*

Device Name
The FMS VUE™ II Fluid Management and Tissue Debridement System

Indications for Use *(Describe)*
The FMS VUE II Fluid Management and Tissue Debridement System is intended to provide controlled fluid distention and suction, controlled cutting, burring, shaving and abrading of bone and tissue for use in arthroscopic surgery of the shoulder, knee, ankle, elbow, wrist and hip joints.

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.

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

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510(k) SUMMARY
FMS VUE™ II FLUID MANAGEMENT AND TISSUE DEBRIDEMENT SYSTEM

Date Prepared: 1/17/2018

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:	FMS VUE™ II Fluid Management and Tissue Debridement System
	Classification Name:	Arthroscope accessory Class II, product code HRX, 21 CFR 888.1100
	Common Name:	Arthroscopic Pump

Substantial Equivalence Predicate Devices

The FMS VUE™ II Fluid Management and Tissue Debridement System is substantially equivalent to:

- The FMS VUE™ Fluid Management and Tissue Debridement System (K130169) (DePuy Mitek)

Device Description

The FMS VUE™ II Fluid Management and Tissue Debridement System is an arthroscopic pump system designed to provide optimal visibility of the surgical field by computer-controlled fluid regulation of intra-articular pressure during arthroscopic procedures.

The FMS VUE™ II Fluid Management and Tissue Debridement System consists of irrigation pump, which controls joint pressure, and the suction pump, which controls the flow of saline and waste from the joint.

The FMS VUE™ II Fluid Management and Tissue Debridement System includes an integrated shaver console, intended to provide controlled cutting, burring, shaving and abrading of bone and soft tissue.

Indications for Use	The FMS VUE™ II Fluid Management and Tissue Debridement System is intended to provide controlled fluid distention and suction, controlled cutting, burring, shaving and abrading of bone and tissue for use in arthroscopic surgery of the shoulder, knee, ankle, elbow, wrist and hip joints.
Technological Characteristics and Performance	The determination of substantial equivalence for this device was based on a detailed device description, performance data, and conformance to consensus and voluntary standards. The FMS VUE™ II Fluid Management and Tissue Debridement System is similar to the predicate DePuy Mitek's FMS VUE™ Fluid Management and Tissue Debridement System (K130169) in that they share the same intended use, and contain inflow and outflow pumps with an integrated shaver control. The FMS VUE™ II Fluid Management and Tissue Debridement System contains updates in the software and hardware, which include updated pressure and debridement settings, and an updated pressure control with joint pressure estimation. FMS VUE™ II Fluid Management and Tissue Debridement System testing included functional performance, joint pressure estimation and control, software verification and validation and testing per IEC 60601-1 and IEC 60601-1-2 standards. Results of functional performance testing were compared to the predicate device and have demonstrated that the proposed device is suitable for its intended use. The testing of re-usable set-up of tubing accessory containing one-way valve included the dye leak testing, and microbial and viral ingress testing.
Conclusion	Based on similarities in the intended use, technological characteristics, IEC 60601-1/ IEC 60601-2 compliance and functional performance in comparison to the predicate device, the FMS VUE™ II Fluid Management and Tissue Debridement System has been shown to be substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.