February 26, 2024

DePuy Mitek, Inc.
Pol Fort Grebol
Project Manager Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K233675
Trade/Device Name: FMS VUE™ Fluid Management and Tissue Debridement System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: November 16, 2023
Received: January 23, 2024

Dear Pol Fort Grebol:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jesse Muir -S Digitally signed by Jesse Muir -S
Date: 2024.02.26 10:05:17 -05'00'

Jesse Muir, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233675

Device Name

FMS VUE™ Fluid Management and Tissue Debridement System

Indications for Use *(Describe)*

The FMS VUE™ 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

Submitter's Name and Address	DePuy Mitek, Inc. 325 Paramount Drive Raynham, MA 02767, USA
Contact Person	Pol Fort Grèbol Project Manager Regulatory Affairs DePuy Synthes *a Johnson & Johnson company* Phone: +34 672 672 579 Email: pfortgre@its.jnj.com
Date Prepared	February 22, 2023
Proprietary Name	FMS VUE™ Fluid Management and Tissue Debridement System
Common or Usual Name	Arthroscopic Pump, Tubing Sets and Accessories
Regulation Number	21 CFR § 888.1100 (Arthroscope)
Regulatory Class	Class II
Product Code	HRX
Predicate Device	The FMS VUE Fluid Management and Tissue Debridement System (K130169) No reference devices were used in this submission.
Device Description Summary	The FMS VUE 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, and flow during arthroscopic procedures. The system integrates a tissue debridement for controlled cutting, burring, shaving and abrading of bone and soft tissue. The FMS VUE 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 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. The FMS VUE Fluid Management and Tissue Debridement System is designed to work with the existing FMS VUE platform accessories including: foot pedal, remote hand control, shaver handpieces, FMS connect cable, tubing sets, blades, and burrs.

<table>
<tr><td></td><td>The FMS VUE Fluid Management and Tissue Debridement System contains updates in the hardware, which include replaced near obsolescence components and new real panel connectors.
The FMS VUE Fluid Management and Tissue Debridement System software modification includes an additional shaver oscillation profile algorithm.</td></tr>
<tr><td>Intended Use / Indications for Use</td><td>The FMS VUE 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.</td></tr>
<tr><td>Indications for Use Comparison</td><td>The proposed device has the same indications for use as the predicate device.</td></tr>
<tr><td>Comparison of Technological Characteristics with the Predicate Device</td><td>Device comparison demonstrated that the subject FMS VUE Fluid Management and Tissue Debridement System is substantially equivalent to the previously cleared FMS VUE Fluid Management and Tissue Debridement System (K130169) regarding intended use, indications for use, technological characteristics (design features and performance) as well as operating principle.
<table>
<tr><th>Characteristic</th><th>Subject Device
FMS VUE Fluid Management and Tissue Debridement System</th><th>Predicate Device
FMS VUE Fluid Management and Tissue Debridement System (K130169)</th></tr>
<tr><td>Product Code</td><td>Same as the predicate device.</td><td>HRX</td></tr>
<tr><td>Intended Use/Indications for Use Statement</td><td>Same as the predicate device.</td><td>The FMS VUE 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.</td></tr>
<tr><td>Contraindications</td><td>Same as the predicate device.</td><td>The FMS VUE System is contraindicated in any non-arthroscopic surgical procedure and is for use with saline irrigation only. The system is not</td></tr>
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			appropriate for patients for whom an arthroscopic procedure is contraindicated for any reason. • DO NOT use the FMS VUE in instances where capsular integrity is suspect. • DO NOT use the FMS VUE with a gas distension medium. Use only with sterile irrigation solution for distension of the operative site. • DO NOT use the FMS VUE to administer drugs, IV-fluids, blood or blood substitutes.
	Principles of Operation	Same as the predicate device.	The device is controlled by software and microelectronics that execute control algorithms that ensure the set pump pressure is being achieved.
	Energy Source	Same as the predicate device.	Supply voltage provided to the console is that of a typical business or hospital environment
	Pump Mechanism	Same as the predicate device.	Two peristaltic pumps: 1 inflow and 1 outflow
	Functional Mode	Same as the predicate device.	• DUO Mode (Inflow/Outflow) • SOLO Mode (Inflow only)
	Roller Wheel	Same as the predicate device.	The device has internally mounted roller wheels that interface with disposable tubing sets.

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<tr><td>Design</td><td>Same as the predicate device.</td><td>Pump consists of the following main components:
Console housing
Power supply
Two peristaltic pumps
Tubing pinch valve
Display panel</td></tr>
<tr><td>Software Development</td><td>Same as the predicate device.</td><td>IEC 62304</td></tr>
<tr><td>Electrical Safety and Electromagnetic Compatibility</td><td>Same as the predicate device.</td><td>IEC 60601-1
IEC 60601-1-2</td></tr>
</table>
The core functionality of the predicate FMS VUE Fluid Management and Tissue Debridement System K130169, as cleared per K130169, remains unchanged. Similarly, the indications for use and intended use remain unchanged.
The changes described in this premarket notification are related to hardware and software upgrades.
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<td>Non-clinical and Clinical Performance Data</td>
<td>
Design verification and validation testing were performed on the subject FMS VUE Fluid Management and Tissue Debridement System as a result of the risk analysis and product requirements.
Proposed FMS VUE Fluid Management and Tissue Debridement System testing included functional performance, 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.
Functional Performance Testing
Functional performance testing was conducted to ensure the device design meets user needs in the environment of use:

Pressure Transducer Test
Pressure Security Test (Low Pressure Fault Checks and High Pressure Fault Checks)
DUO (Inflow/Outflow) Performance
SOLO (Inflow) Performance
RFID Capability
Functional Testing with existing electrical accessories:

Foot Pedal
Remote Hand Control

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	○ Shaver Handpieces ○ FMS Connect Cable • Backflow-Prevention Valve Testing (Dye Leak Testing) • Microbial and Viral Ingress Testing **Software Verification and Validation** Software verification and validation testing was conducted, and documentation was provided as recommended by Guidance for Industry and FDA Staff "Content of Premarket Submission for Device Software Functions" issued on June 14, 2023. Based on the cited FDA guidance document, the most appropriate documentation level for the subject FMS VUE software is Basic Documentation. The software development process for the subject FMS VUE Fluid Management and Tissue Debridement System software conforms to all clauses of IEC 62304 standard. **Electrical Safety and Electromagnetic Compatibility (EMC)** Electrical safety and EMC testing were conducted on the predicate FMS VUE Fluid Management and Tissue Debridement System and results provided as part of the original 510(k) submission, K130169. The subject FMS VUE Fluid Management and Tissue Debridement System complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC. **Animal Study** No animal testing was conducted to determine the safety and effectiveness of the FMS VUE Fluid Management and Tissue Debridement System. **Clinical Studies** No human clinical testing was conducted to determine the safety and effectiveness of the FMS VUE Fluid Management and Tissue Debridement System.
Substantial Equivalence	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 testing included in this submission demonstrates that: • Any differences in technological characteristics of the predicate devices do not raise any new questions of safety or effectiveness. • The proposed devices are at least as safe and effective as the predicate devices.
Conclusion	The intended use, design principles, and fundamental technology of the subject FMS VUE Fluid Management and Tissue Debridement System remains unchanged and therefore is substantially equivalent to the predicate device – the FMS VUE Fluid Management and Tissue Debridement System (K130169). The proposed hardware and software modifications do not raise new questions of safety or effectiveness of the subject FMS VUE Fluid Management and Tissue Debridement System. The results of the non-clinical performance testing conducted supports the safety of the device and

	demonstrates that proposed FMS VUE performs as intended in the specified use conditions.