December 5, 2025

W.O.M. World of Medicine GmbH
Lisa Kober
Lead Regulatory Affairs Specialist
Salzufer 8
10587 Berlin
Germany

Re: K250795
Trade/Device Name: PUREVUE™ FMS
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: November 10, 2025
Received: November 10, 2025

Dear Mrs. Lisa Kober:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.12.05 11:33:35 -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
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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.*

510(k) Number *(if known)*
K250795

Device Name
PUREVUE™ FMS

Indications for Use *(Describe)*
The PUREVUE™ FMS is a dual arthroscopic pump system intended to provide fluid distension and irrigation of knee, shoulder, hip, elbow, ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic 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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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| **Contact Details** | **21 CFR 807.92(a)(1)** |
|---|---|
| Applicant Name | W.O.M. World of Medicine GmbH |
| Applicant Address | Salzufer 8, 10587 Berlin, Germany |
| Applicant Contact Telephone | +4930-399 81-625 |
| Applicant Contact | Mrs. Lisa Kober |
| Applicant Contact Email | Lisa.kober@novanta.com |

| **Device Name** | **21 CFR 807.92(a)(2)** |
|---|---|
| Device Trade Name | PUREVUE™ FMS |
| Common Name | Pump |
| Classification Name | Arthroscope |
| Regulation Number | 888.1100 |
| Product Code(s) | HRX |

| **Legally Marketed Predicate Devices** | **21 CFR 807.92(a)(3)** |
|---|---|
| Predicate # | K123441 |
| Predicate Trade Name | Stryker CrossFlow Integrated Arthroscopy Pump |
| Product Code | HRX |

**Device Description Summary (21 CFR 807.92(a)(4)):**

The PUREVUE™ FMS is an arthroscopy pump with irrigation and suction function. The device is equipped with two independent peristaltic pump systems and can be used both as an irrigation pump and as a suction pump. This provides two options for operating the unit: the Single roller mode and the Dual roller mode.

Single roller mode (Inflow): In this mode, the Inflow Cassette Tube transmits fluid from saline bags to the inflow cannula or sheath at the surgical site.

Dual roller mode (Inflow/Outflow): This mode uses both the inflow and outflow functions of the pump via the Inflow Cassette Tube and Outflow Cassette Tube.

The device is non-invasive and designed to be placed in non-sterile areas.

The PUREVUE™ FMS is a dual arthroscopic pump system intended to provide fluid distension and irrigation of knee, shoulder, hip, elbow, ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures.

The PUREVUE™ FMS is a fluid management system based on the peristaltic principle that provides irrigation and suction functionalities for arthroscopic procedures. Along with its accessories (Tube set for irrigation (single-use), Tube set for suction (2-lines, single-use), Day use tube set for irrigation (pump part, 10 applications), Patient tube for irrigation (single-use), Tube set for suction (1-line, single-use), Tube set inflow 4-spike adaptor, Tube set for vacuum incl. filter (30-day use, reusable), autoclavable remote control and double foot switch), the device delivers medical sterile irrigation fluid from fluid bags to the cavity. This distends the cavity to create space for the procedure. In addition, the device along with its accessories can aspirate fluid from the patient's cavity to improve the visibility.

**Intended Use/Indications for Use (21 CFR 807.92(a)(5)):**

The PUREVUE™ FMS is a dual arthroscopic pump system intended to provide fluid distension and irrigation of knee, shoulder, hip, elbow, ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures.

**Indications for Use Comparison (21 CFR 807.92(a)(5):**

The PUREVUE™ FMS has the same indications for use as the predicate device Stryker CrossFlow Integrated Arthroscopy Pump:

*The Stryker CrossFlow Integrated Arthroscopy Pump is a dual arthroscopic pump system intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures.*

**Technological Comparison (21 CFR 807.92(a)(6)):**

The Stryker CrossFlow Integrated Arthroscopy Pump is the predicate device for the subject device PUREVUE™ FMS (PA124). Both pumps are for use during arthroscopic procedures and have the same basic design. They are both dual roller pumps that function according to the peristaltic principle and are to be used with specially designed tube sets. Both pumps are software controlled to ensure that the set pressure is being achieved and maintained in the patient´s joint.

The features offered by the subject device, as well as the default pressure settings and flow rate ranges differ from the predicate slightly. However, as the subject device adopts more conservative limits for these ranges and as every feature is verified through performance testing, these differences do not raise any different questions of safety & effectiveness over the predicate. The subject device does provide an integrated vacuum pump and offers related suction tube sets to provide an additional vacuum source as an option for the user.

The differences in the technological characteristics of both the PUREVUE™ FMS and the predicate device Stryker CrossFlow Integrated Arthroscopy Pump are minor and do not raise different questions of safety and effectiveness.

**Non-Clinical and/or Clinical Tests Summary & Conclusions (21 CFR 807.92(b)):**

The performance and safety of the PUREVUE™ FMS was tested in accordance with design specifications and recognized consensus standards. The electrical safety of the PUREVUE™ FMS is tested according to IEC 60601-1 Edition 3.2 (2020) and electromagnetic compatibility according to IEC 60601-1-2 Edition 4.1 (2020). The software was developed, tested, and verified as per IEC 62304:2015.

The tube sets are sterilized according to ISO 11135:2018 and their biocompatibility was tested per ISO 10993-1:2018 standard series for indirect patient contacting materials. The Day Use Tube Set was tested as recommended by the FDA guidance "Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use - Premarket Notification (510(k)) Submissions".

Furthermore, bench performance testing was performed on the PUREVUE™ FMS to verify that device specifications are met and the device functions as intended and indicated.

Based on the same indications for use, similar technological characteristics, performance testing and comparison to the predicate device, the PUREVUE™ FMS raises no new questions of safety and effectiveness. We conclude that the proposed device is substantially equivalent to the predicate device.