March 9, 2023

Hemodia SAS
% Arne Briest
Managing Director
VisaMed GmbH
Kastellstr. 8
Karlsruhe, 76227
Germany

Re: K221919
Trade/Device Name: DOUBLEFLO INFLOW/OUTFLOW PUMP, accessories and tubing sets
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: February 7, 2023
Received: February 7, 2023

Dear Arne Briest:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Sara S. Thompson -S

For

Laurence D. Coyne, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221919

Device Name
DOUBLEFLO INFLOW/OUTFLOW PUMP, accessories and tubing sets

Indications for Use *(Describe)*
The DOUBLEFLO INFLOW/OUTFLOW PUMP, accessories and tubing sets represents an arthroscopy system using fluid from saline bags (0.9% NaCl). This arthroscopy system is intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle and wrist joint cavities, and fluid suction during arthroscopy 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.

K221919
510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part §807.92 upon which substantial equivalence is based.

I SUBMISSION SPONSOR and APPLICATION CORRESPONDANT

A. SUBMISSION SPONSOR

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II. Dated prepared: March 9, 2023

III DEVICE IDENTIFICATION

Name of Device:	**DOUBLEFLO INFLOW/OUTFLOW PUMP**, accessories and tubing sets
Common Name:	Pump (Arthroscopy pump)
Classification Name:	Arthroscope (21 CFR § 888.1100)
Classification Panel:	Orthopedic
Regulatory Class (pump and tubings) :	II
Product Code:	HRX
510k #:	K221919

IV PREDICATE DEVICE

Predicate Device	**K203480** - DOUBLEFLO System
Reference Device	**K192921** - ZEOS Aqua Vision Pump and tubing sets

V. DEVICE DESCRIPTION

The **DOUBLEFLO INFLOW/OUTFLOW PUMP** is a micro-processor controlled pump that functions according to the peristaltic principle. It transports sterile irrigation fluid to distend cavities and provides fluid aspiration for arthroscopic procedures. The pump connects via cable to various interfaces.

The pump can be connected to various accessories / shaver systems.

The pump has to be used with the following tube sets:

Tubing Sets		
Product Category	**Model Designation**	**Part Number**
Tubing Set	DOUBLEFLO DAY TUBE SET	**72205772**
Tubing Set	DOUBLEFLO PATIENT TUBE SET	**72205773**
Tubing Set	DOUBLEFLO INFLOW TUBE SET	**72205774**
Tubing Set	DOUBLEFLO OUTFLOW TUBE SET	**72205765**

VI INDICATIONS FOR USE

The **DOUBLEFLO INFLOW/OUTFLOW PUMP**, accessories and tubing sets represents an arthroscopy system using fluid from saline bags (0.9%NaCl). This arthroscopy system is intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle and wrist joint cavities, and fluid suction during arthroscopy procedures.

VII COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The **DOUBLEFLO system** (K203480) is the predicate device for the **DOUBLEFLO INFLOW/OUTFLOW PUMP**, accessories and tubing sets**.**

Each pump systems mentioned above are designed, developed and manufactured using the same general design principles and similar mechanical and electrical components.
They have the same intended use and incorporate the same basic design. Specifically, each predicates devices and **DOUBLEFLO INFLOW/OUTFLOW PUMP**, accessories and tubing sets are for use during arthroscopic procedures to provide fluid irrigation and aspiration. They are roller pumps that function according to the peristaltic principle and are to be used with specially designed tube sets.

The **DOUBLEFLO System,** and the **DOUBLEFLO INFLOW/OUTFLOW PUMP**, accessories and tubing sets are designed to be used with compatible accessories.

The features and technical characteristics that differ from the previous version of DOUBLEFLO system (K203480 - pump, with associated accessories and tubing sets) manufactured by HEMODIA SAS, and that are considered in this 510(k) submission are:

- Addition of **compatible pump accessories**: addition of a Remote, Foot Control Interfaces, Hand Control Interfaces, Footswitch, and Power Cords,
- The **DOUBLEFLO INFLOW/OUTFLOW PUMP** is now equipped with a **tubing recognition system**. This system allows precise traceability of the tubing, allows the control of the use of the tubing (e.g. the pump use a pre-programmed algorithm according to the tubing used: DOUBLEFLO DAY TUBE SET or DOUBLEFLO INFLOW TUBE SET or the pump discard outdated tubing), but also allows protection against copying. This technical solution is made possible by the addition of an RFID (Radio Frequency Identification) reader on the **DOUBLEFLO INFLOW/OUTFLOW PUMP** and a label on each tubing (RFID Tag containing encrypted data),
- **Software revision**, to implement the tubing recognition using RFID system (reader and RFID tag), to correct anomalies, and a further improved compensation of pressure losses,
- Modification of the **design of the pinch valve** of the **DOUBLEFLO INFLOW/OUTFLOW PUMP**,
- **Addition of new components** (RFID label) and **raw material changes** for the tubing.

- **Packaging change** for the tubing sets
- **Adjusted shelf-life** for the OUTFLOW TUBING SETS (Ref: 72205765)

These new technical characteristics do not lead to differences between these predicate devices and subject device considering the clinical and technical support of the intended use. The functionalities of the **DOUBLEFLO INFLOW/OUTFLOW PUMP**, accessories and tubing sets remain the same.

Conclusion: The differences in the technological characteristics of the predicate device, **DOUBLEFLO system** and the **DOUBLEFLO INFLOW/OUTFLOW PUMP**, accessories and tubing sets are minor and do not raise different questions of safety and effectiveness.

VIII PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Software

The software was developed, tested, and verified in accordance with the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and in accordance with the following standard:

• IEC62304- Medical Device Software – Software Life Cycle Processes.

Software tests were conducted to satisfy the requirements of the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and IEC 62304 Standard (Medical Device Software – Life Cycle Process). The software was considered as a “moderate” level of concern, since a failure or latent design flaw could directly result in minor injury to the patient or operator or could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Software verification activities were performed during the "Design, coding & testing" and "Verification" phases of software lifecycle. Outputs generated during these phases include:

- Unit test reports
- Integration test reports

- System test reports
- Overall software test report
- Verification test reports
- Overall software validation report

The software tests at the unit, integration and system levels were performed according to the Software Test Plan. Verification tests were performed for each software requirement according to the Software Verification Plan.

Conformity of software with the user needs and intended use of the device were performed through the "Validation" phase of the **DOUBLEFLO INFLOW/OUTFLOW PUMP,** accessories and tubing sets.

Design verification testing of the **DOUBLEFLO INFLOW/OUTFLOW PUMP,** accessories and tubing sets demonstrates that the device performs as intended and that the performance does not raise different questions of safety and effectiveness.

Electrical safety and electromagnetic compatibility

Electrical safety and electromagnetic compatibility (EMC) testing were conducted on the **DOUBLEFLO INFLOW/OUTFLOW PUMP**, and associated accessories.

The device complies with recognized electrical safety standards:

- IEC 60601-1 standard for electrical safety
- IEC 60601-1-2 standard for electromagnetic compatibility.

Biocompatibility testing

The biocompatibility evaluation for DOUBLEFLO tubing sets has been conducted in accordance with FDA Guidance Document: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" and ISO 10993-1 – "Biological evaluation of medical devices – Evaluation and testing within a risk management system". These **tubing sets** are categorized as externally communicating devices in indirect contact with tissue/bone for a limited time (<24h) *per* ISO 10993-1. The evaluation reveals that biocompatibility requirements are met by the **DOUBLEFLO INFLOW/OUTFLOW PUMP** tubing sets.

Biocompatibility testing was performed on the tube sets in accordance with:

• ISO 10993-1 - Biological evaluation of medical devices- Evaluation and testing within a risk management system;
• ISO 10993-5 - Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity; and
• ISO 10993-10 - Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization;
• ISO 10993-11 - Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity.
• European Pharmacopeia ISO 10993-12
• United States Pharmacopoeia 42 – National Formulary 37 (USP 42-NF 37 ISO 10993-12)

Sterilization Validation

In addition, the sterilization validation on the tube sets has been performed in accordance with:

- ISO 11135 - Sterilization of health care products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical device
- ISO 11135-1 - Sterilization of health care products – Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices;
- ISO 14937 - Sterilization of health care products - General criteria for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices; and
- ISO 10993-7 - Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) data shows that the limit of EO < 4 mg and ECH < 5 mg after 3 days of aeration (gas release) that remain on the tube set will not be exceeded. The sterility assurance level (SAL) was 10^{-6}. Package and product integrity of the tube sets were tested in accordance with ISO11607-1 - Packaging for terminally sterilized medical devices and ASTM-F- 1980:2002 - Standard for accelerated aging of sterile medical device packages.

Performance Testing - Bench

The following performance tests were conducted:

- Functional tests of the **DOUBLEFLO INFLOW/OUTFLOW PUMP**
- Functional tests of the **DOUBLEFLO INFLOW/OUTFLOW PUMP, accessories**
- Usability Tests of the **DOUBLEFLO INFLOW/OUTFLOW PUMP** , accessories and tubing.
- Functional tests of the tubing sets at t_0 and after 18 months (for the DOUBLEFLO OUTFLOW TUBE SET, Ref: 72205765) and 3 years of accelerated aging (for the DOUBLEFLO DAY TUBE SET, DOUBLEFLO PATIENT TUBE SET, AND DOUBLEFLO INFLOW TUBE SET)
- Leak and Tensile (Strength) tests of the tubing sets at t_0 and after 18 months (for the **DOUBLEFLO INFLOW/OUTFLOW PUMP** OUTFLOW TUBE SET, Ref: 72205765) and 3 years of accelerated aging (for the DOUBLEFLO DAY TUBE SET, **DOUBLEFLO INFLOW/OUTFLOW PUMP** PATIENT TUBE SET, AND **DOUBLEFLO INFLOW/OUTFLOW PUMP** INFLOW TUBE SET)

Animal studies

Data from animal studies were not required to support the safety and effectiveness of the **DOUBLEFLO INFLOW/OUTFLOW PUMP,** accessories and tubing sets.

Clinical Studies

Clinical data were not required to support the safety and effectiveness of the **DOUBLEFLO INFLOW/OUTFLOW PUMP**, accessories and tubing sets. All validation was performed based on non-clinical performance tests.

IX SUMMARY OF NON CLINICAL PERFORMANCE TESTING - Bench

Test	Test Method Summary	Results
Electrical safety and electromagnetic compatibility (EMC)	Testing in compliance with the IEC 60601-1 and IEC 60601-1-2	Evaluation and testing were performed on the subject device and demonstrated to be substantially equivalent to the predicate devices. Addition of the RFID (reader and tag) related test requirements.
Biocompatibility testing	Testing in compliance with FDA Guidance "Use of International Standard ISO 10993, Biological evaluation of medical Devices Part 1" and ISO 10993-1	The following non clinical tests were performed on the subject or equivalent devices: Cytotoxicity, Sensitization, Irritation, Acute systemic toxicity and Pyrogenicity and demonstrated to be substantially equivalent to the predicate devices.
Software Verification and Validation Testing	Software verification testing in compliance with FDA guidance "General Principles of Software Validation" and IEC 62304	Evaluation and testing were performed on the subject device and demonstrated substantially equivalent performance to identified predicate devices. The testing successfully cover RFID (reader and tag) related test requirements.
Sterilization Validation	The sterilization validation was performed according to ISO 11135 and ISO 11135-1 Sterilization of health care products – Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices; and • ISO 10993-7 - Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.	Validation was performed on the subject device and demonstrated to be substantially equivalent to the identified predicate devices.
Bench Tests	The functional and usability tests on **DOUBLEFLO INFLOW/OUTFLOW PUMP**, accessories and tubing sets were performed according to	Evaluation and testing were performed on the subject device and demonstrated substantially

	IEC 62366 – Medical Devices – Part 1: Application of Usability Engineering to Medical to Medical Devices. The functional test included test on the strength of the tubing sets at t_0 and following three years and 3 months of accelerated aging.	equivalent performance to identified predicate devices.
Animal studies	Not applicable	Not applicable
Clinical Studies	Not applicable	Not applicable

X CONCLUSIONS

Based on the same intended use, the same basic technological characteristics and performance testing, the **DOUBLEFLO INFLOW/OUTFLOW PUMP,** accessories and tubing sets is substantially equivalent to the predicate device **DOUBLEFLO System** (K203480). The differences between the proposed device and the predicate device do not raise different questions of safety and effectiveness.