April 5, 2021

Hemodia SAS
% Arne Briest
Managing Director
VISAMED GmbH
Kastellstr. 8
Karlsruhe76227
Germany

Re: K203480/S001
Trade/Device Name: DOUBLEFLO system
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: March 5, 2021
Received: March 8, 2021

Dear Mr. 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,

Laura C. Rose -S

Laura C. Rose, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K203480

Device Name
DOUBLEFLO system

Indications for Use *(Describe)*

The DOUBLEFLO system 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)

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K203480

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

HEMODIA SAS

85 rue du Chêne vert
31670 Labège – France

www.hemodia.com

Tel +33 (0) 5 61 00 03 50

Contact Person :

Adeline Théron

Regulatory Affairs Engineer

adeline.theron@hemodia.com

B. APPLICATION CORRESPONDANT

VISAMED GmbH
Kastellstr. 8
D-76227 Karlsruhe-Germany

www.visamed.com

Tel +49 (0) 721 476 4847

Contact Person :

Arne Briest

CEO

arne.briest@visamed.com

II. Dated prepared: April 5, 2021

III DEVICE IDENTIFICATION

Name of Device:	**DOUBLEFLO system**
Common Name:	Pump (Arthroscopy pump)
Classification Name:	Arthroscope (21 CFR § 888.1100)
Classification Panel:	Orthopedic
Regulatory Class:	II
Product Code:	HRX
510k #:	K203480

IV PREDICATE DEVICE

K192921 - ZEOS Aqua Vision Pump and tubing sets

V. DEVICE DESCRIPTION

The **DOUBLEFLO system** (pump) contains as a main component 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 shaver systems.

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

Tubing Sets		
Product Category	**Model Designation**	**Part Number**
Tubing Set	DAY TUBE Set	72205353
Tubing Set	Patient Tube Set	72205354
Tubing Set	Inflow Tube Set	72205355
Tubing Set	Outflow Tube Set	72205356

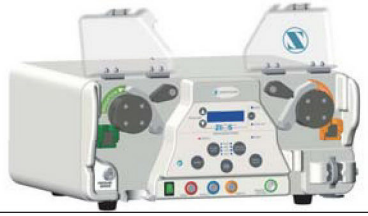
VI INDICATIONS FOR USE

The **DOUBLEFLO system** 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 **ZEOS Aqua Vision Pump** is the predicate device for the **DOUBLEFLO system** (pump, tubing sets and accessories).

Both pump systems 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, both the **ZEOS Aqua Vision Pump** and tubing sets and the **DOUBLEFLO system** are for use during arthroscopic procedures to provide fluid irrigation and aspiration. They are both roller pumps that function according to the peristaltic principle and are to be used with specially designed tube sets.

	Predicate Devices	Subject Device	Comparison Analysis
Device	**ZEOS Aqua Vision Pump** (K192921)	**DOUBLEFLO system** (K203480)	-
Description and Indication for Use			
Illustration			Similar overall set up and user interface, identical principle of operations
General Device Description	Dual Pump Arthroscopic System, the irrigation/aspiration system has a common control system with two separate pumps, one pump dedicated to irrigation and one pump dedicated to aspiration.	Dual Pump Arthroscopic System, the irrigation/aspiration system has a common control system with two separate pumps, one pump dedicated to irrigation and one pump dedicated to aspiration.	**Identical**
Technical Characteristics			
Principle of operation	Microprocessor controlled Roller Pump and automatic fluid management	Microprocessor controlled Roller Pump and automatic fluid management	**Identical**
Irrigation and suction in one unit: independent inflow/outflow control	Yes, two separate irrigation / aspiration pumps	Yes, two separate irrigation / aspiration pumps	**Identical**

	Predicate Devices	Subject Device	Comparison Analysis
Regulates pressure and flow	yes	yes	**Substantially equivalent,** the only difference is that the subject device maintains the pressure constant when the flow rate is changed.
Maximum allowable pressure	280 mmHg	150 mmHg	The maximum preset pressure allowable by the **DOUBLEFLO system** software is lower than that of the **ZEOS AQUA VISION pump**.
Minimum allowable pressure	20 mmHg	5 mmHg	**Substantially equivalent.**
Default pressure at start of the pump	60 mmHg	50 mmHg	**Substantially equivalent.** The default pressures defined by the **DOUBLEFLO system** software is lower than that of the **ZEOS AQUA VISION** pump.

<table>
<tr><th></th><th>Predicate Devices</th><th>Subject Device</th><th>Comparison Analysis</th></tr>
<tr><td>Recommended initial pressure setting</td><td>
<table>
<tr><th rowspan="2">Joint</th><th colspan="2">Pressure level with tourniquet</th><th colspan="2">Pressure level without tourniquet</th><th>FLUSH RATE</th><th>Shaver suction</th></tr>
<tr><th>mmHg</th><th>LH2O</th><th>mmHg</th><th>LH2O</th><th>/</th><th>/</th></tr>
<tr><td>Shoulder joint</td><td>/</td><td>/</td><td>60</td><td>30</td><td>Low or Med</td><td>Low or Med</td></tr>
<tr><td>Acromioplasty</td><td>/</td><td>/</td><td>60</td><td>30</td><td>Low or Med</td><td>Med or High</td></tr>
<tr><td>Knee scope</td><td>30
50-60</td><td>10
20-30</td><td>65
50-60</td><td>30
20-30</td><td>Low or Med
Low or Med</td><td>Low or Med
Med or High</td></tr>
<tr><td>Wrist</td><td>30</td><td>10</td><td>65</td><td>30</td><td>Low or Med</td><td>Low or Med</td></tr>
<tr><td>Elbow, ankle</td><td>40</td><td>20</td><td>65</td><td>30</td><td>Low or Med</td><td>Low or Med</td></tr>
<tr><td>Hip</td><td>/</td><td>/</td><td>65</td><td>30</td><td>Low or Med</td><td>Low or Med</td></tr>
</table>
</td><td>
<table>
<tr><th>Joint</th><th>Pressure level with tourniquet</th><th>Pressure level without tourniquet</th><th>RINSE SUCTION</th><th>SHAVER SUCTION</th></tr>
<tr><td></td><td>mmHg</td><td>mmHg</td><td>/</td><td>/</td></tr>
<tr><td>Shoulder joint</td><td>/</td><td>60</td><td>Low or Med</td><td>Low or Med</td></tr>
<tr><td>Acromioplasty</td><td>/</td><td>60</td><td>Low or Med</td><td>Med or High</td></tr>
<tr><td>Knee scope</td><td>30
50-60</td><td>65
50-60</td><td>Low or Med
Low or Med</td><td>Low or Med
Med or High</td></tr>
<tr><td>Wrist</td><td>30</td><td>65</td><td>Low or Med</td><td>Low or Med</td></tr>
<tr><td>Elbow, ankle</td><td>40</td><td>65</td><td>Low or Med</td><td>Low or Med</td></tr>
<tr><td>Hip</td><td>/</td><td>65</td><td>Low or Med</td><td>Low or Med</td></tr>
</table>
</td><td>Identical</td></tr>
<tr><td>Pressure Rate Security Hardware</td><td>375 mmHg</td><td>280 ± 10mmHg</td><td>Substantially equivalent</td></tr>
<tr><td>Flow Rate</td><td>There are 4 flow rates for the Cannula suction and 4 flow rates for the Shaver Suction -> displayed by LED (MIN, LOW, MED and HIGH)</td><td>There are 3 flow rates for the Cannula suction and 3 flow rates for the Shaver Suction -> displayed by LED (LOW, MED and HIGH)</td><td>Substantially equivalent</td></tr>
<tr><td>Minimum flow rate</td><td>Cannula 100 mL/min
Shaver: 200 mL/min</td><td>Cannula flow rates: 100 mL/min
Shaver flow rates: 200 mL/min</td><td>Identical</td></tr>
<tr><td>Maximum flow rate</td><td>Cannula 600 mL/min
Shaver: 800mL/min</td><td>Cannula flow rates: 600 mL/min
Shaver flow rates: 800 mL/min</td><td>Identical</td></tr>
<tr><td>Interfaces</td><td>Interface with various shaver systems and various footswitches</td><td>Interface with a Shaver Interface Cable</td><td>Substantially equivalent, subject device has additional interfaces no more functionalities</td></tr>
</table>

	Predicate Devices	Subject Device	Comparison Analysis
Control with Footswitch	Yes, Footswitch (wired)	No	**Substantially equivalent**, subject device has other control such as keyboard (front panel interface, and foot switch from the shaver when connected via Shaver Interface Cable)
Control with Remote	No	No	**Identical**
Consumable	Polymer Tubing	Polymer Tubing	**Substantially equivalent**

The differences in the technological characteristics of both the proposed device **ZEOS Aqua Vision Pump** and tubing sets and the **DOUBLEFLO system** is minor and do not raise new questions of safety and effectiveness.

There is no technical characteristics that differs between these devices when considering the clinical and technical support of the intended use.

Both the **ZEOS Aqua Vision Pump** and tubing sets and the **DOUBLEFLO system** are designed to be used with compatible shaver systems.

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 system**.

Design verification testing of the **DOUBLEFLO system** demonstrates that the device performs as intended and that the performance does not raise new questions of safety and effectiveness.

Electrical safety and electromagnetic compatibility

Electrical safety and electromagnetic compatibility (EMC) testing were conducted on the **DOUBLEFLO system**.

The device complies with recognized electrical safety standards:

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

hemodia
Medical Partner

Biocompatibility testing

The biocompatibility evaluation for **DOUBLEFLO system** 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 system** 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.

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 system**
- Functional tests of the **DOUBLEFLO system** accessories
- Usability Tests of the **DOUBLEFLO system**
- Functional tests of the tubing sets at t_0 and after 3 years of accelerated aging
- Leak and Tensile (Strength) tests of the tubing sets at t_0 and after 3 years of accelerated aging

Animal studies

Data from animal studies were not required to support the safety and effectiveness of the **DOUBLEFLO system**.

Clinical Studies

Clinical data were not required to support the safety and effectiveness of the **DOUBLEFLO system**. 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 device.
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 and Acute systemic toxicity and demonstrated to be substantially equivalent to the predicate device.
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 device
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 the **DOUBLEFLO system** was performed according to IEC 62366 – Medical Devices –	Evaluation and testing were performed on the subject device and demonstrated substantially equivalent performance to identified predicate device.

	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.	
Animal studies	Not applicable	Not applicable
Clinical Studies	Not applicable	Not applicable

X CONCLUSIONS

Based on the similar intended use, the same basic technological characteristics and performance testing, the **DOUBLEFLO system (**pump, tubing sets and accessories**)** is substantially equivalent to the predicate device **ZEOS Aqua Vision Pump and tubing sets** (K192921). The differences between the proposed device and the predicate device do not raise new questions of safety and effectiveness.