October 9, 2020

Hemodia SAS
℅ Arne Briest
Managing Director
VISAMED GmbH
Kastellstr. 8
Karlsruhe, 76227 De

Re: K192921
Trade/Device Name: ZEOS AQUA VISION PUMP and tube
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: September 4, 2020
Received: September 8, 2020

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,

for

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)*
K192921

Device Name
ZEOS AQUA VISION PUMP

Indications for Use *(Describe)*

The ZEOS AQUA VISION Pump is an arthroscopy pump system 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)*

# 510(k) Summary

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

## I SUBMISSION SPONSOR and APPLICATION CORRESPONDANT

### A. SUBMISSION SPONSOR

**HEMODIDA 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:** October 11, 2019

## III DEVICE IDENTIFICATION

| | |
|---|---|
| **Name of Device**: | **ZEOS AQUA VISION PUMP and tube** |
| **Common Name**: | Pump (Arthroscopy pump) |
| **Classification Name:** | Arthroscope (21 CFR § 888.1100) |
| **Classification Panel:** | Orthopedic |
| **Regulatory Class:** | II |
| **Product Code:** | HRX |
| **510k #:** | TBD |

## IV PREDICATE DEVICE

- **K130169** - FMS VUE Fluid Management & Tissue Debridement System; FMS Connect Interface Cable

## V. DEVICE DESCRIPTION

The **ZEOS AQUA VISION 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 shaver systems.

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

| Tubing | | |
|---|---|---|
| **Product Category** | **Model Designation** | **Part Number** |
| Tubing | ZEOS AQUA VISION EFFICIENT CARE DAY TUBE | ZAVECDAY |
| Tubing | ZEOS AQUA VISION EFFICIENT CARE INFLOW/OUTFLOW SET | ZAVECSET |
| Tubing | ZEOS AQUA VISION EFFICIENT CARE INFLOW ONLY | ZAVECINF |
| Tubing | ZEOS AQUA VISION EFFICIENT CARE OUTFLOW ONLY | ZAVECOUT |
| Tubing | ZEOS AQUA VISION PATIENT CARE INFLOW/OUTFLOW SET | ZAVPCSET |
| Tubing | ZEOS AQUA VISION PATIENT CARE INFLOW ONLY | ZAVPCINF |
| Tubing | ZEOS AQUA VISION PATIENT CARE OUTFLOW ONLY | ZAVPCOUT |

## VI INDICATIONS FOR USE

The ZEOS AQUA VISION Pump is an arthroscopy pump system 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 **FMS VUE Fluid Management & Tissue Debridement System** is the predicate device for the **ZEOS AQUA VISION** pump and tubing sets.

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 FMS VUE Fluid Management & Tissue Debridement System and the **ZEOS AQUA VISION** pump and tubing sets are pumps 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.

The differences in the technological characteristics of both the proposed device FMS VUE Fluid Management & Tissue Debridement System and the **ZEOS AQUA VISION** pump and tubing sets are minor and do not raise new questions of safety and effectiveness.

Both the FMS VUE Fluid Management & Tissue Debridement System and the **ZEOS AQUA VISION** pump and tubing sets 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 **ZEOS AQUA VISION** pump device.

Design verification testing of the **ZEOS AQUA VISION** pump 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 was conducted on the **ZEOS AQUA VISION** pump.

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 **ZEOS AQUA VISION tube 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". The evaluation reveals that biocompatibility requirements are met by the ZEOS AQUA VISION tube 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 **ZEOS AQUA Vision** pump
- Functional tests of the **ZEOS AQUA Vision** pump accessories
- Usability Tests of the **ZEOS AQUA Vision** pump system
- Functional tests of the tubing sets at $t_0$ and after 3 years and 3 months of accelerated aging
- Leak and Tensile (Strength) tests of the tubing sets at $t_0$ and after 3 years and 3 months of accelerated aging

**Animal studies**

Data from animal studies were not required to support the safety and effectiveness of the **ZEOS AQUA VISION PUMP**.

**Clinical Studies**

Clinical data were not required to support the safety and effectiveness of the **ZEOS AQUA VISION PUMP**. 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 device: 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<br>• 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 ZEOS AQUA Vision pump system were 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 **ZEOS AQUA VISION PUMP** is substantially equivalent to the predicate device FMS VUE Fluid Management & Tissue Debridement System (K130169). The differences between the proposed device and the predicate device do not raise new questions of safety and effectiveness.