January 15, 2020

Eberle GmbH & Co. KG
℅ Arne Briest
Managing Director
VISAMED GmbH
Kastellstr. 8
Karlsruhe, 76227 Germany

Re: K193608/S002
Trade/Device Name: EBERLE Shaver System C3 and Accessories
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: December 18, 2020
Received: December 18, 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,

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)*
K193608

Device Name
EBERLE Shaver System C3

Indications for Use *(Describe)*

The EBERLE shaver system C3 is a powered instrument system and consists of a control unit, a footswitch, a handpiece and accessories. It is designed for arthroscopy surgical procedures like shaving, burring, abrading, cutting and resecting of fibrous tissue, cartilage tissue and bone.

The EBERLE shaver system accessories are designed to use with the EBERLE shaver system for arthroscopy surgical procedures like shaving, burring, abrading, cutting, drilling and resecting of fibrous tissue, cartilage tissue and bone."

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.

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EBERLE

K193608

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

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Contact Person:

Arne Briest

CEO

arne.briest@visamed.com

II. Dated prepared: December 17, 2020

III DEVICE IDENTIFICATION

Proprietary Name of Device:	**Eberle Shaver System C3**
Common Name:	Surgical Shaver and Accessories
Classification Name:	Arthroscope and Accessories (21 CFR § 888.1100)
Classification Panel:	Orthopedic
Regulatory Class:	II
Product Code:	HRX
510k #:	K193608

IV PREDICATE DEVICE

- **K061134** - Eberle Shaver System C2 and Shaver Blades
- **K092977** - Eberle Shaver System Accessories

V. DEVICE DESCRIPTION

The **EBERLE Shaver System C3** and shaver blades is a powered instrument system and consists of a control unit, a foot switch, handpiece(s), and accessories – associated sterile shaver blades for single use.

The control unit C3 includes three software systems. The other components of the shaver system C3 e.g. handpiece or footswitch consist only of hardware components. All software systems on the control unit are running on microcontrollers.

The Eberle Shaver Blades consists of an outer tube with a hub and a rotating inner tube with a connector. The inner and outer tube consists of stainless steel. The hub and connector consist of Polyoxymethylen (POM), the tubes consists of stainless steel. The shaver blades are provided in a sterile packaging and are intended for single use. The shaver blades are sterilized using EO sterilization with a Sterilization Assurance Level (SAL) of 10^{-6}.

The Eberle Handpieces with switch buttons have three buttons to select the direction of rotation depending on the user assignment of functionalities to the buttons. It consists of Stainless Steel and Aluminum.

The Eberle Drill and the Saw – Handpieces also consist of Stainless Steel and Aluminum. The Drill Handpiece has two buttons to select the direction of rotation and the saw has an operator lever.

All these components are designed, constructed and intended to be operated exclusively as a system. EBERLE Shaver System C2 and C3 use the same shaver blades. The shaver blades are identical with the once already cleared under the predicated device K092977 - Eberle Shaver System Accessories. Eberle has added addition blades to provide a broader offering.

EBERLE Shaver System C2 and C3 have common handpieces and use the same kind of adapters.

VI INDICATIONS FOR USE

The **EBERLE Shaver System C3** is a powered instrument system and consists of a control unit, a footswitch, a handpiece and accessories. It is designed for arthroscopy surgical procedures like shaving, burring, abrading, cutting and resecting of fibrous tissue, cartilage tissue and bone.

The **EBERLE Shaver System accessories** are designed to be used with the EBERLE Shaver System for arthroscopy surgical procedures like shaving, burring, abrading, cutting, drilling and resecting of fibrous tissue, cartilage tissue and bone.

VII COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The **EBERLE Shaver System C2** and Shaver Blades **and the EBERLE Shaver System** accessories are the predicate devices for the **EBERLE Shaver System C3** and shaver blades.

Both Eberle Shaver Systems and Shaver Blades 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 EBERLE Shaver System C2 and the **EBERLE Shaver System C3** and shaver blades are used for arthroscopy surgical procedures like shaving, burring, abrading, cutting, drilling and resecting of fibrous tissue, cartilage tissue and bone.

Software and Hardware

The **EBERLE Shaver System C3** has additional software functionalities (rotation and frequency based oscillation modus, increased max. speed of 10.000 min^{-1}, improved rpm accuracy of +/- 5%, functionality of buttons of the footswitch and handpiece can be free assigned) when compared to the **EBERLE Shaver System C2**. In addition the two handpiece connectors are identical. Both connectors can used for all **EBERLE handpieces**.
The **EBERLE Shaver System C3** utilizes a new faster processors - (model name: Atmel ATxmega256A3U). The programing languages C was utilized for both the **EBERLE Shaver System C2** and **EBERLE Shaver System C3**.

Handpieces

The EBERLE Shaver system handpieces for the C2 and C3 system are available with stainless steel or aluminum housing. The housing design was optimized for the C3 handpieces to reduce the weight. The main benefit of the handpieces with stainless steel housing is the higher resistance against potential mechanical damage. The hand pieces with an aluminum housing are lighter. The handpieces are available with and without control buttons. The functionalities are identical. The connector cable was changed to adapt to the new connectors of the C3 control units.
The brushless DC motors used in the C2 and C3 handpieces use identical materials and are identical in design components. The handpieces for the C3 are using a new gearbox to reach higher rotational speed (rpm; 10.000 min^{-1}).

Adapter

Eberle has added new adapter made of the same material than the previous cleared adapter under the predicated device. The new adapters are designed to adapt more closer to selected drill or wire diameter. In addition a drill chuck adapters is offered with key less fixation.

The universal handpiece can be used with the following adapters:

- Drill chuck adapter, high-power, 0.7-7.4 mm
- Drill chuck adapter, 0-3.0 mm, keyless
- Sagittal saw adapter
- Wire driver adapter, 1.8-3.2mm
- Drill chuck adapter 0.7-7.4 mm
- Wire driver adapter, 0.6-1.8 mm

The method of operations and the design are substantial equivalent.

Footswitch

The footswitch for the C2 has four buttons. The functionalities were preassign and programed to the buttons. The oscillation mode was activated by pressing two button´s at the same time. The footswitch used for the C3 has five buttons. The functionalities can be freely assigned to the buttons. The additional button can be used to activate the oscillation mode.

Conclusion

The differences in the technological characteristics of both the predicate devices and the proposed device EBERLE Shaver System C2 and shaver blades and the EBERLE Shaver System Accessories and the **EBERLE Shaver System C3** and shaver blades are minor and do not raise new questions of safety and effectiveness.

Both the EBERLE Shaver System C2 and shaver blades and the EBERLE Shaver System Accessories and the **EBERLE Shaver System C3** and shaver slades are designed to be used with compatible shavers from Eberle.

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.

Software verification activities were performed during the "Integration & Testing" and "Verification" and “Validation” phases of software lifecycle.

Outputs generated during these phases include:

- Software and Hardware Requirements Specification
- Software Description
- Architecture Design Chart
- Software Design Specification (SDS)
- Risk management
- Traceability Matrix
- Verification and Validation test plans and test reports
- Revision Level History
- Unresolved Anomalies

The software tests during the "Integration & Testing" and "Verification" and “Validation” phases of software lifecycle 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 **EBERLE Shaver System C3** device.

Design verification testing of the **EBERLE Shaver System C3** 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 **EBERLE Shaver System C3**.

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 EBERLE handpieces, adapters and shaver blades 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 EBERLE handpieces, adapters and shaver blades.

Biocompatibility testing was performed in accordance with:

- ISO 10993-1 - Biological evaluation of medical devices- Evaluation and testing within a risk management system;
- ISO 10993-4 - Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
- 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.

Ethylene Oxide (Single Use Devices)

In addition, the sterilization validation on the **EBERLE Shavers** 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 show that the limit of EO < 4 mg and ECH < 9 mg after 1 day of aeration (gas release) that remain on the **EBERLE Shavers** will not be exceeded. The sterility assurance level (SAL) was 10^{-6}. Package and product integrity of the shaver blades were tested in accordance with ISO11607-1 - Packaging for terminally sterilized medical devices.

Cleaning and Sterilization Validation (Reusable Devices)

Eberle has performed for the handpieces and adapters (attachments) an cleaning and sterilization validation.

Performance Testing - Bench

The following performance tests were conducted:

- Performance of Handpieces and Shaver Blades within Intended Use
- Control of Handpiece Speed by Eberle Shaver System C3
- Performance of Handpiece Adapter
- Performance Test – Shelf Life of Shaver Blades

Animal studies

Data from animal studies were not required to support the safety and effectiveness of the **EBERLE Shaver System C3 and Shaver Blades**.

Clinical Studies

Clinical data were not required to support the safety and effectiveness of the **EBERLE Shaver System C3** and shaver blades. 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 • 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 **EBERLE Shaver System C3 and Shaver Blades** were performed according to IEC 62366 – Medical Devices – Part 1: Application of Usability Engineering to Medical to Medical Devices.	Evaluation and testing were performed on the subject device and demonstrated substantially equivalent performance to identified predicate device.
Animal studies	Not applicable	Not applicable
Clinical Studies	Not applicable	Not applicable

X Overall CONCLUSIONS

Based on the similar intended use, the same basic technological characteristics and performance testing, the **EBERLE Shaver System C3** and shaver blades is substantially equivalent to the predicate devices **EBERLE Shaver System C2** and shaver blades and **the EBERLE Shaver System** accessories. The differences between the proposed device and the predicate device do not raise new questions of safety and effectiveness.