February, 27, 2024

Maquet Cardiovascular, LLC
Timothy Rice
Regulatory Affairs Specialist II
45 Barbour Pond Road
Wayne, New Jersey 07470

RE: K233879
Trade/Device Name: Vasoview Hemopro 3 Endoscopic Vessel Harvesting System (VH-6000), Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield (VH-6001), and Vasoview Hemopro 3 Power Adapter (VH-6020)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 6, 2023
Received: December 8, 2023

Dear Mr. Rice:

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.02.27 13:25:28 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233879

Device Name
Vasoview Hemopro 3 Endoscopic Vessel Harvesting System, Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield & Vasoview Hemopro 3 Power Adapter

Indications for Use *(Describe)*

The Vasoview Hemopro 3 System is indicated for use in minimally invasive surgery allowing access for vessel harvesting and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. It is indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or the radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.

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.

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510(k) Summary - K233879

Submitter: Maquet Cardiovascular, LLC

Address: 45 Barbour Pond Rd
Wayne NJ 07470
United States

Contact Person: Timothy Rice
(888) 627-8383
timothy.rice@getinge.com

Date Prepared: February 26, 2024

Device Trade Name: *Vasoview Hemopro 3 Endoscopic Vessel Harvesting System*
Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield
Vasoview Hemopro 3 Power Adapter

Common Name: Electrosurgical cutting and coagulation device accessories

Classification Name: Electrosurgical cutting and coagulation device accessories

Regulation Number: 878.4400

Product Code: GEI

Class: II

Legally Marketed Predicate Device(s)	510(k) Number	Product Code
Vasoview Hemopro 2 Endoscopic Vessel Harvesting System	K101274	GEI

Device Description:

The Vasoview Hemopro 3 Endoscopic Vessel Harvesting System is designed for use in conjunction with the 7 mm Endoscope. The Harvesting Cannula has four lumens which house the Endoscope, C-Ring, distal lens washer tube and Vasoview Hemopro 3 Harvesting Tool for cutting and cauterization of vessel branches. The C-Ring with the built-in distal lens washer is independently controlled by a C-Ring Slider on the handle of the Harvesting Cannula. The C-Ring cradles the vessel and delivers the saline that washes the distal tip of the Endoscope.

The Harvesting Tool can be inserted, removed, rotated, extended, and retracted from the main Harvesting Cannula through the Tool Adapter Port.

The Harvesting Tool is powered by direct current (DC) only; it does not utilize RF (radio frequency) energy. The Harvesting Tool cuts and cauterizes through a process of heat and pressure. The Harvesting Tool has two curved Jaws. One of the Jaws contains the heating elements for branch cutting and cauterization and spot cautery. There are three heating elements: two cauterization elements and a cutting element between them. Both Jaws have insulation protecting the adjacent tissue. The concave side of the Jaws has a larger buffer of insulation and therefore should be positioned toward sensitive tissue during Jaw activation. An area near the tip of the convex side of the Jaw can be used for spot cautery to cauterize tissue contacted by that area of the Jaw.

The Activation Toggle is used to control the Jaws and to activate the heating elements. Positioning of the device, cutting, and cauterization are performed under endoscopic visualization. This device is intended for specific use with the Vasoview Hemopro Power Supply and Vasoview Hemopro 3 Power Adapter.

Intended Use/Indications for Use:

The Vasoview Hemopro 3 System is indicated for use in minimally invasive surgery allowing access for vessel harvesting and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. It is indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or the radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.

Indications for Use Comparison:

Maquet's Vasoview Hemopro 3 Endoscopic Vessel Harvesting System has the same Indications for Use as the predicate device, Vasoview Hemopro 2 Endoscopic Vessel Harvesting System

Comparison of Technological Characteristics with the Predicate Device:

The subject device (Vasoview Hemopro 3 Endoscopic Vessel Harvesting System, Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield, and Vasoview Hemopro 3 Power Adapter) and the predicate device have the following similarities:

- The same intended use
- The same operating principles
- The same basic design
- The same sterilization method
- The same sterile barrier packaging material

The subject device incorporates the following modifications:

- Improved Harvesting Tool handle design and ergonomics and increased durability
- Improved Cannula interface and increased visibility
- C-Ring material change to provide better heat resistance

The design verification/validation testing demonstrates that the Hemopro 3 Endoscopic Vessel Harvesting System Cannula has similar technological characteristics compared to the Hemopro 2 Endoscopic Vessel Harvesting System Cannula, or in the case where differences are noted, such differences do not raise new or different questions of safety or effectiveness. Such conclusions are also supported by the successful design validation and summative usability studies conducted and included in the submission.

Non-Clinical and/or Clinical Tests Summary:

Biocompatibility Testing:

The biocompatibility evaluation for Vasoview Hemopro 3 Endoscopic Vessel Harvesting System and Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield was conducted in accordance with ISO 10993-1 and FDA Guidance for Industry and Food and Drug Administration Staff *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* The Vasoview Hemopro 3 EVH Systems are considered as an externally communicating device with limited contact (≤24 hours) to tissue/bone. The patient-contacting components of the subject device are classified as tissue contact and do not have direct or indirect contact with circulating blood. The following biological evaluations were performed:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Vasoview Hemopro 3 Endoscopic Vessel Harvesting System, Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield, and Hemopro Power Supply. The subject device complies with the following electrical safety performance standards:

- *IEC 60601-1:2005 + Amendment 1and 2* - Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

- *IEC 60601-1-2: 2014 Amendment 1* - Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests - Ed 4.1

- *IEC 60601-1-6:2010 Amendment 1and 2*- Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

- *IEC 60601-2-18:2009* - Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment (identical to BS EN 60601-2-18:2015)

Sterilization/Shelf-Life

The Vasoview Hemopro 3 Endoscopic Vessel Harvesting (EVH) System and Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield were validated to achieve a sterility assurance level of 10^{-6} using gamma irradiation as per ISO 11137. The designated shelf life for the Vasoview Hemopro 3 EVH System will be two years.

Mechanical/Bench Testing
The following design verification testing was conducted:

- Tool and Cannula Mechanical Evaluation
    - Tool and Cannula Handle Ergonomics
    - Cannula Interface Ergonomics
    - Dimensional Analysis
    - Jaw Mechanical Attributes
    - Device Durability

- Tool Electrical Evaluation
    - Energy Delivery and Durability

- Packaging/Sterile Barrier Evaluation
- Power Adapter Functional and Cycle Life Evaluation
- Thermal Spread Evaluation
- Vessel Burst Pressure

Design verification was performed to demonstrate that the Vasoview Hemopro 3 EVH devices perform as intended and claimed. The results of the verification/validation testing demonstrate that the Vasoview Hemopro 3 device meets the established acceptance criteria and performs in a manner substantially equivalent to the predicate device.

Animal Testing
A GLP design validation study was conducted utilizing porcine models and incorporating end user evaluation. The evaluation conducted demonstrated that the subject device, Vasoview Hemopro

3 EVH System, meets end user needs and did not raise additional safety or performance concerns.

Human Factors Validation Testing
A summative human factors validation study was conducted in compliance with FDA Guidance for Industry and FDA Staff *Applying Human Factors and Usability Engineering to Medical Devices*, issued February 3, 2016, and IEC 62366- 1:2015/AMD 1:2020 Medical devices – Part 1: Application of usability engineering to medical devices + Amendment 1. The study demonstrated that the Vasoview Hemopro 3 EVH System is adequately designed and found to be safe and effective for the intended users, user interfaces, and use environments. Based on the usability validation test results, no unacceptable residual risks from a usability perspective remain after the summative usability validation; thereby, no further reduction of risks by modification is deemed necessary. The therapy benefit outweighs the risk for the entirety of the device.

Substantial Equivalence:
The Vasoview Hemopro 3 Endoscopic Vessel Harvesting System, Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield, and Vasoview Hemopro 3 Power Adapter have similar technological and functional characteristics as the predicate device. Both devices are sterile, single use devices and have the same intended use and sterile barrier. The performance data demonstrate that the subject device is as safe and effective as its predicate device. Based on these performance data, the technological differences between the subject device and its predicate do not raise new or different questions of safety or effectiveness. As such, the Vasoview Hemopro 3 Endoscopic Vessel Harvesting System, Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield, and Vasoview Hemopro 3 Power Adapter are substantially equivalent to the predicate device.

Conclusion:
The Vasoview Hemopro 3 Endoscopic Vessel Harvesting System, Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield, and Vasoview Hemopro 3 Power Adapter have the same intended use and Indications for Use and similar technological characteristics as the predicate device. The technological differences between the subject device and the predicate device raise no new or different questions of safety or effectiveness. Hence, the subject device is substantially equivalent to the predicate device that is currently marketed for the same intended use.