February 26, 2025

Maquet Cardiovascular, LLC
Brad Sheals
Sr. Manager, Regulatory Affairs
45 Barbour Pond Rd.
Wayne, New Jersey 07470

RE: K243918
Trade/Device Name: Vasoview Hemopro 3 Power Supply
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 19, 2024
Received: December 20, 2024

Dear Brad Sheals:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.02.26 23:08:18 -05'00'

For
Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243918

Device Name
Vasoview Hemopro 3 Power Supply

Indications for Use *(Describe)*

The Vasoview Hemopro 3 Power Supply is used in conjunction with the Vasoview Hemopro 3 Endoscopic Vessel Harvesting System, which 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary - K243918

Submitter:	Maquet Cardiovascular, LLC
Address:	45 Barbour Pond Rd Wayne, NJ 07470 United States
Contact Person:	Mr. Brad Sheals, MS 901-286-0318 brad.sheals@getinge.com
Date Prepared:	February 25, 2025
Device Trade Name:	Vasoview Hemopro 3 Power Supply
Common Name:	Electrosurgical cutting and coagulation device accessories
Classification Name:	Electrosurgical cutting and coagulation device accessories
Regulation Number:	878.4400
Product Code:	GEI
Classification Panel:	General and Plastic Surgery
Class:	II

Legally Marketed Predicate Device(s)	**510(k) Number**	**Product Code**
Vasoview Hemopro 3 Endoscopic Vessel Harvesting System	K233879	GEI
Starion Universal Power Supply	K043155	HQO

Device Description:

The Vasoview Hemopro 3 Power Supply is a reusable, AC-powered device intended to be used only with the Vasoview Hemopro 3 Endoscopic Vessel Harvesting System. The Vasoview Hemopro 3 Power Supply provides DC current to the Vasoview Hemopro 3 Harvesting Tool to enable cutting and coagulation of vessels and tissue during vessel harvesting procedures. The Vasoview Hemopro 3 Power Supply is positioned outside the sterile field, and can be placed on a flat, non-sterile surface or may be suspended from a nearby IV pole. The Vasoview Hemopro 3 Power Supply does not make contact with the patient, nor does it deliver energy directly to the patient; energy to the patient is delivered by the Vasoview Hemopro 3 Harvesting Tool. The Vasoview Hemopro 3 Power Supply is intended to be used by healthcare professionals in an operating room environment.

Principles of Operation:
The Vasoview Hemopro 3 Power Supply is connected to AC power via a hospital grade power cord and features an on/off switch and green power-on LED indicator. DC output power is delivered to the Vasoview Hemopro 3 Endoscopic Vessel Harvesting System when the Vasoview Hemopro 3 Harvesting Tool Activation Toggle is activated. The Vasoview Hemopro 3 Power Supply does not produce RF energy. When activated, an energy-regulating circuit within the Vasoview Hemopro 3 Power Supply controls the energy delivery to the Vasoview Hemopro 3 Harvesting Tool to perform its cut/coagulation cycle.

Intended Use/Indications for Use:

The Vasoview Hemopro 3 Power Supply is used in conjunction with the Vasoview Hemopro 3 Endoscopic Vessel Harvesting System, which 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:

The indications for use for the Vasoview Hemopro 3 Power Supply are the same as for the predicate devices: Starion Universal Power Supply and the Vasoview Hemopro Power Supply and Vasoview Hemopro 3 Power Adapter components of the Vasoview Hemopro 3 Endoscopic Vessel Harvesting System.

Comparison of Technological Characteristics with the Predicate Device:

The subject device (Vasoview Hemopro 3 Power Supply) has the same technological characteristics as the predicate devices: Starion Universal Power Supply and the Vasoview Hemopro Power Supply and Vasoview Hemopro 3 Power Adapter components of the Vasoview Hemopro 3 Endoscopic Vessel Harvesting System.

The subject device and the predicate devices have the following similarities:

- The same intended use

- The same operating principles

- The same technological characteristics

- The same DC current output

The subject device incorporates the following modifications:

- Fixed DC energy output versus variable DC energy output

Design verification/validation testing demonstrates that the Vasoview Hemopro 3 Power Supply has similar technological characteristics compared to the predicate Starion Universal Power Supply and the Vasoview Hemopro Power Supply and Vasoview Hemopro 3 Power Adapter components of the Vasoview Hemopro 3 Endoscopic Vessel Harvesting System. 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.

Summary of Nonclinical and/or Clinical Tests:

Design verification and validation were performed to demonstrate that the Vasoview Hemopro 3 Power Supply performs as intended and claimed. The results of the verification/validation testing demonstrate that the Vasoview Hemopro 3 Power Supply meets the established acceptance criteria and performs in a manner equivalent to the predicate device. No new safety or effectiveness issues were raised during the testing.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Vasoview Hemopro 3 Power Supply in connection with Vasoview Hemopro 3 Endoscopic Vessel Harvesting Tool, and the subject device complies with the following electrical safety performance standards:

- ANSI/AAMI ES60601-1:2005/A2:2021
- ES60601-1:2005/AMD1 1:2012
- ES60601-1:2005/AMD2:2021
- IEC 60601-1-6:2010/AMD2:2020
- IEC 60601-1-2: 2018

Human Factors / Usability

A summative human factors validation study was conducted in compliance with FDA guidance “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 purpose of this human factors validation test was to validate the usability, user interface, and use-safety of the subject device (Vasoview Hemopro 3 Power Supply) with the Vasoview Hemopro 3 Endoscopic Vessel Harvesting System, including instructions for use and training. The study demonstrated that the Vasoview Hemopro 3 Power Supply is adequately designed and found to be safe and effective for the intended users, uses, and use environments. Based on the usability validation test results, no unacceptable residual risks from a usability perspective remain, and no further reduction of risks by modification was deemed necessary.

Clinical Testing

No clinical testing was conducted in support of this submission. Please note that FDA Guidance "Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation" does not apply as this device is not indicated for such use.

Bench Testing

The following design verification and validation testing were conducted:

- Electrical Life Cycle Design Verification
- Mechanical Life Cycle Verification
- Connection Force and Activation Cycle Verification
- Life Cycle Durability Testing (inclusive of design-specific characterization)
- Cleaning and Disinfection Validation
- Wet Handling Verification
- Packaging and Labeling Verification
- Labeling and Markings Legibility, Adherence, and Durability Testing
- Shipping/Transit Life Cycle Verification

The following consensus standards were used or referenced as applicable in the bench testing performed:

- ISO 15223-1 Fourth Edition 2021-07
- ISO 20417 First edition 2021-04 Corrected version 2021-12
- ISO 14971 Third Edition 2019-12
- ISO 17664-2 First edition 2021-02
- ASTM F2825-18
- ASTM D4169-22
- ANSI/AAMI HE75:2009/(R)2018

Conclusion:

Based on similarities in the indications for use and technological and functional characteristics and the results of nonclinical performance tests, the Vasoview Hemopro 3 Power Supply is substantially equivalent to the predicate devices.