May 30, 2025

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

RE: K251238
Trade/Device Name: Vasoview Hemopro 3 Endoscopic Vessel Harvesting System (VH-6000); Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield (VH-6001); Vasoview Hemopro 3 Power Supply (VH-6010)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 21, 2025
Received: April 22, 2025

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-devicese/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: 2025.05.30 17:20:06 -04'00'

James Jang, Ph.D.
Acting 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)*
K251238

Device Name
Vasoview Hemopro 3 Endoscopic Vessel Harvesting System
Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield
Vasoview Hemopro 3 Power Supply

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.

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

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.

510(k) Summary - K251238

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: May 30, 2025

Device Trade Name: Vasoview Hemopro 3 Endoscopic Vessel Harvesting System
Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield
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 2 Endoscopic Vessel Harvesting System	K101274	GEI
Vasoview Hemopro 3 Endoscopic Vessel Harvesting System	K233879	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 only; it does not utilize radiofrequency 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 should, therefore, 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 3 Power Supply.

Model numbers applicable to the Vasoview Hemopro 3 System are:

- VH-6000 – Vasoview Hemopro 3 Endoscopic Vessel Harvesting System
- VH-6001 – Vasoview Hemopro 3 Endoscopic Vessel Harvesting System with Vasoshield
- VH-6010 – Vasoview Hemopro 3 Power Supply

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.

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

Indications for Use Comparison:

The indications for use for the subject Vasoview Hemopro 3 Endoscopic Vessel Harvesting System are the same as for the predicate devices: Vasoview Hemopro 3 Endoscopic Vessel Harvesting System and the Vasoview Hemopro 2 Endoscopic Vessel Harvesting System.

Comparison of Technological Characteristics with the Predicate Devices:

The subject device (Vasoview Hemopro 3 Endoscopic Vessel Harvesting System) has the same intended use and similar technological characteristics as those of the predicate devices:

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

The subject device incorporates the following modifications:

- Material change to the C-Ring component of the Hemopro 3 Endoscopic Vessel Harvesting System Cannula

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

Summary of Nonclinical and/or Clinical Tests:

Testing was performed to demonstrate that the material change to the C-Ring component of the Hemopro 3 System's Cannula subassembly does not affect the device's ability to perform as intended. No new safety or effectiveness issues were raised during the testing.

Bench Testing

The following design verification and validation tests were conducted:

- Mechanical and Thermal Characterization of C-Rings
- C-Ring Temperature Durability and Mechanical Strength
- C-Ring Extreme Use Cadaver Testing
- Technical Report - HP3 C-Ring Change Justifications

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

- ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
- ANSI/AAMI HE75:2009/(R)2018
- IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version
- IEC 60601-1-6 Edition 3.2 2020-07 Consolidated Version
- 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

- ISO 11137-3 Second edition 2017-06
- ASTM D4169-22

Clinical Testing

No clinical testing was conducted in support of this submission.

Conclusion:

Based on similarities in the indications for use and technological characteristics and on the results of nonclinical performance tests, the modified Vasoview Hemopro 3 Endoscopic Vessel Harvesting System is found substantially equivalent to the predicate devices.