DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 19, 2016

MAQUET Cardiovascular, LLC
Mr. Mark Dinger
Sr. Regulatory Affairs Specialist
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K153194
Trade/Device Name: Vasoview Hemopro Endoscopic Vessel Harvesting System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 30, 2016
Received: March 31, 2016

Dear Mr. Dinger:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K153194

Device Name
VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System

Indications for Use *(Describe)*
The VASOVIEW HEMOPRO 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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MAQUET
GETINGE GROUP

VASOVIEW HemoPro Endoscopic Vessel Harvesting System

510(k) Summary

Prepared in accordance with 21 CFR Part 807.92

510(k) Number: K153194

Date Prepared: 30 October 2015

Device Owner:
MAQUET Cardiovascular LLC
45 Barbour Pond Drive
Wayne, New Jersey 07470

Contact Personnel: Mr. Mark Dinger, B.S.
Title: Sr. Regulatory Affairs Specialist
Email: mark.dinger@maquet.com
Phone: 973-709-7691 **Fax:** 973-909-9954

Trade Name: VASOVIEW HemoPro Endoscopic Vessel Harvesting System

Device Generic Name: Electrosurgical cutting and coagulation device and accessories

Classification: According to 21 CFR 878.4400 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Product code GEI.

Predicate Device: K052274 VASOVIEW HemoPro Endoscopic Vessel Harvesting System (SE: 21 September 2005)

Device Description: The VASOVIEW HEMOPRO 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 Harvesting Tool for cutting and sealing of vessel branches. The C-Ring/distal lens washer is independently controlled by a C‑Ring Slider on the handle of the device that retracts the vessel and washes the distal tip of the Endoscope. The Harvesting Tool can be extended/retracted from the main cannula by inserting it into the Tool Adapter Port, and rotated independently. The Harvesting Tool has two curved Jaws. One Jaw contains the heating elements for branch cutting and sealing; the second Jaw is longer and has a

	serrated inner edge. Cutting and sealing of vessel branches is achieved in two steps: (1) capture of the branch between the HEMOPRO Jaws, and (2) simultaneous coagulation and ligation of the branch with the Jaws using direct current. Both steps are achieved by mechanical application of the Activation Toggle. Positioning of the device, cutting, and sealing are performed under endoscopic visualization. This device is intended for specific use with the VASOVIEW HEMOPRO Power Supply.
Indications for Use:	The VASOVIEW HEMOPRO 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.
Technological Characteristics	The Proposed HemoPro and the predicate devices have the following similarities: o the same intended use, o the same operating principles, o incorporates the same basic design, o sterilized using the same materials and processes, o has same packaging. The Proposed HemoPro and the predicate devices have the following differences: A redesign of the electrical system in the HemoPro Tool from a Logic to a Power Switch system using the following internal components: o Switch UMB: 5 Amps@ 125/250 VAC

- Toggle and Spring Toggle Return in the Toggle Assembly.
- Molded handle halves with modified Pad prints.
- Pigtail adapter plug: To accommodate the electrical pigtail of the HemoPro tool, a new part required to capture the pigtail with the handle halves.

The differences are not considered a technological difference and are substantially equivalent to the predicate device.

Safety and Performance:

MAQUET Cardiovascular's development process required that the following activities be completed during the development of the HemoPro:

- Performance testing
- Burst Pressure testing
- Thermal Spread testing
- Electrical Testing 60601-1
- Shelf life testing

The results of the in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the currently marketed VASOVIEW HemoPro Endoscopic Vessel Harvesting System.

The reason for this 510(k) is to address the MDR issues identified as self activated /remains activated and overheating.

Conclusion:

Based upon the information submitted in this Traditional 510(k) premarket notification, MAQUET's VASOVIEW HemoPro Endoscopic Vessel Harvesting System is substantially equivalent to the currently marketed predicate device. The VASOVIEW HemoPro Endoscopic Vessel Harvesting System is similar to the predicate devices in the intended use and the fundamental scientific technology of the device. The performance and other testing established that the VASOVIEW HemoPro Endoscopic Vessel Harvesting System is substantially equivalent as the predicate device.