September 17, 2019

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

Re: K191947
Trade/Device Name: VASOVIEW HEMOPRO Extension Cable, VASOVIEW HEMOPRO 2 Extension Cable, Bipolar Extension Cable, Fixed Distance, and Active Return Cord
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 19, 2019
Received: July 22, 2019

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. 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 and Part 809); 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,

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191947

Device Name
VASOVIEW HEMOPRO Extension Cable, VASOVIEW HEMOPRO 2 Extension Cable, Bipolar Extension Cable, Fixed Distance and Active Return Cord

Indications for Use *(Describe)*
The subject Cables (VASOVIEW HEMOPRO Extension Cable, VASOVIEW HEMOPRO 2 Extension Cable, Bipolar Extension Cable, Fixed Distance and Active Return Cord) are accessories to the VASOVIEW Endoscopic Vessel Harvesting System. They are supplied non-sterile and must be sterilized prior to each.

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

Prepared in accordance with 21 CFR Part 807.92

**510(k) Number:** K191947

**Date Prepared:** 16 Sept 2019

**Device Owner:**
MAQUET Cardiovascular, LLC.
45 Barbour Pond Drive
Wayne NJ 07470
United States of America

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

**Trade Name:** VASOVIEW HEMOPRO Extension Cable, VASOVIEW HEMOPRO 2 Extension Cable, Bipolar Extension Cable, Fixed Distance and Active Return Cord

**Device Generic Name:** Electrosurgical cutting and coagulation device and accessories

**Classification**:
Class II
GEI; Electrosurgical cutting and coagulation device and accessories, 21 CFR 878.4400

**Predicate Device:**
(K153194) VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System (SE: 19 April 2016)

(K101274) VASOVIEW HEMOPRO 2 Endoscopic Vessel Harvesting System (SE: 11 June 2010)

(K091733) VASOVIEW 6 PRO Endoscopic Vessel Harvesting System (SE: 28 August 2009)

**Device Description:**

The VASOVIEW HEMOPRO Extension Cable (P/N VH-3030), is a reusable cable designed for use with the VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System and the VASOVIEW HEMOPRO Power Supply. The Extension Cable is supplied non-sterile and must be sterilized prior to each use.

The VASOVIEW HEMOPRO 2 Extension Cable (P/N VH-4030), is a reusable cable designed for use with the VASOVIEW HEMOPRO 2 Endoscopic Vessel Harvesting System and the VASOVIEW HEMOPRO Power Supply and the HEMOPRO 2 Adapter Cable. The Extension Cable is supplied non-sterile and shall be sterilized prior to each use. The Extension Cable connects to the VASOVIEW HEMOPRO Power Supply via the Adapter Cable.

The Active/Return extension cord with banana plugs (P/N 1838), is a reusable cord designed for use with the VASOVIEW Endoscopic Vessel Harvesting System VV6 Pro/VV7. Each cord is supplied non-sterile and must be sterilized prior to each use.

The Bipolar Extension Cable, Fixed Distance (P/N 2838) is a reusable cable designed for use with the VASOVIEW Endoscopic Vessel Harvesting System VV6 Pro /VV7. Each cable is supplied non-sterile and must be sterilized prior to each use.

**Indications for Use**:

The subject Cables (VASOVIEW HEMOPRO Extension Cable, VASOVIEW HEMOPRO 2 Extension Cable, Bipolar Extension Cable, Fixed Distance and Active Return Cord) are accessories to the VASOVIEW Endoscopic Vessel Harvesting System. They are supplied non-sterile and must be sterilized prior to each.

**Technological Characteristics**

The Proposed Cables and the predicate devices have the following similarities:

- the same intended use,
- the same operating principles,
- incorporates the same basic design and materials,
- has same packaging.

The Proposed Cables and the predicate devices have the following differences:

- Added clarity to the Manual Cleaning method and added the following cleaning methods to provide more flexibility capability to the end user.
  - Manual Cleaning with Sonication
  - Automated Cleaning with Alkaline detergent
  - Automated Cleaning with Enzymatic detergent
  - Combined Automated Washing / Thermal High Level Disinfectant (in a washer/disinfecter).
- Expanded method in one modality and removed a method in

another modality for sterilization.

**TABLE 1: SUBSTANTIAL EQUIVALENCE TABLE**

| **Description** | **(K153194) VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System (SE: 19 April 2016)<br>(K101274) VASOVIEW HEMOPRO 2 Endoscopic Vessel Harvesting System (SE: 11 June 2010)<br>(K091733) VASOVIEW 6 PRO Endoscopic Vessel Harvesting System (SE: 28 August 2009)** | **Proposed Cables** |
|---|---|---|
| Product Code | GEI | Same as Predicate |
| Regulation No. | 21 CFR 878.4400 Electrosurgical cutting and coagulation device and accessories | Same as Predicate |
| Biocompatibility | Materials are reasonably safe and effective for limited duration of an external communicating device for tissue/bone/dentin accordance with international standards ANSI/AAMI/ISO 10993-1<br>• Cytotoxicity<br>• Sensitization<br>• Irritation (including intracutaneous reactivity)<br>• Systemic Toxicity | Same as Predicate |
| Sterility | Sold non-sterile | Same as Predicate |
| Verification | Performance Testing | Same as Predicate |
| Indications For Use | The VASOVIEW 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 subject Cables (VASOVIEW HEMOPRO Extension Cable, VASOVIEW HEMOPRO 2 Extension Cable, Bipolar Extension Cable, Fixed Distance and Active Return Cord) are accessories to the VASOVIEW Endoscopic Vessel Harvesting System. They are supplied non-sterile and must be sterilized prior to each. |
| Target Population | Primarily, patients with cardiovascular disease undergoing surgery, including cardiac and peripheral bypass surgery | Same as Predicate |
| Anatomical Sites | Blood vessels, blood vessels of the extremities, the saphenous vein and the radial artery, structures in the extraperitoneal or subcutaneous extremity and thoracic space, nerves, blood vessels and other tissues of the chest wall. | Same as Predicate |
| Use Location (hospital, home ambulance, ect.) | Hospital | Same as Predicate |

| | | |
|---|---|---|
| Device Description | The VASOVIEW HEMOPRO Extension Cable (P/N VH-3030) is a reusable cable designed for use with the VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System and the VASOVIEW HEMOPRO Power Supply. The Extension Cable is supplied non-sterile and must be sterilized prior to each use.<br><br>The VASOVIEW HEMOPRO 2 Extension Cable (P/N VH-4030) is a reusable cable designed for use with the VASOVIEW HEMOPRO 2 Endoscopic Vessel Harvesting System and the VASOVIEW HEMOPRO Power Supply and the HEMOPRO 2 Adapter Cable. The Extension Cable is supplied non-sterile and shall be sterilized prior to each use. The Extension Cable connects to the VASOVIEW HEMOPRO Power Supply via the Adapter Cable.<br><br>The Active/Return extension cord with banana plugs (P/N 1838), is a reusable cord designed for use with the VASOVIEW Endoscopic Vessel Harvesting System Each cord is supplied non-sterile and must be sterilized prior to each use.<br><br>The Bipolar Extension Cable, Fixed Distance (P/N 2838) is a reusable cable designed for use with the VASOVIEW Endoscopic Vessel Harvesting System. Each cable is supplied non-sterile and must be sterilized prior to each use. | Same as Predicate |
| Cleaning Methods | Cleaning<br>o Manual<br>o Ultrasonic | •Added Clarity to Manual Cleaning method<br>•Manual Cleaning with Sonication<br>•Automated Cleaning with Alkaline detergent<br>•Automated Cleaning with Enzymatic detergent<br>•Combined Automated Washing / Thermal High Level Disinfectant (in a washer/disinfecter). |
| Reprocessing Methods | Sterilization:<br>o Steam<br>o Ethylene Oxide<br>o Steris System 1<br>o Sterrad 100S, NX & 100 NX | Sterilization:<br>o Steam<br>o Ethylene Oxide<br>o Sterrad 100S, NX & 100 NX<br>o Steris VPRO<br>o Sterizone VP4 |

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

**Safety and Performance**: MAQUET Cardiovascular, LLC., development process required that the following activities be completed during the development of the Cables:

| Performance testing |
|---|
| Complex Product Family Manual Cleaning Process Performance Qualification |
| Complex Product Family Manual with Ultrasonic Cleaning Process Performance Qualification |
| Complex Product Family Automated Washer With Alkaline Detergent Cleaning Process Performance Qualification |
| Complex Product Family Automated Washer with Enzyme Detergent Cleaning Process Performance Qualification |
| Complex Product Family Thermal Disinfection Performance Qualification |
| Human Factors Usability Validation – Endoscope |
| Complex Product Family MEM Elution Cytotoxicity Testing for Enzymatic Detergent Residuals Performance Qualification |
| Complex Product Family MEM Elution Cytotoxicity Testing for Alkaline Detergent Residuals Performance Qualification |
| Complex Product Family Sterizone VP4 Sterilization Process Performance Qualification |
| Complex Product Family Steris® V-Pro™ 1 Plus Hydrogen Peroxide Sterilization Process Performance Qualification |
| Complex Product Family Ethylene Oxide Sterilization Process Performance Qualification |
| Complex Product Family Steam Sterilization Process Performance Qualification |

The results of the in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the previously cleared Cables.

**Conclusion:**

Based upon the information submitted in this Traditional 510(k) premarket notification, MAQUET Cardiovascular's Cables are substantially equivalent to the predicate device. The Cables are similar to the predicate devices in the intended use and the fundamental scientific technology of the device. The performance testing established that the Cables are substantially equivalent as the predicate device.