K101274

JUN 11 2010

510(k) SUMMARY

Submitter	MAQUET Cardiovascular
Submitter's Address	170 Baytech Road San Jose, CA 95134
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Contact Person	Mark H. Smith
Date Prepared	March 19, 2010
Device Trade Name	VASOVIEW HEMOPRO 2 Endoscopic Vessel Harvesting System
Device Common Name	Electrosurgical cutting and coagulation device and accessories
Device Classification Name	Electrosurgical cutting and coagulation device and accessories
Device Classification	Class II
Summary of substantial equivalence	The design, materials, method of delivery, and intended use features of the VASOVIEW HEMOPRO 2 Endoscopic Vessel Harvesting System are substantially equivalent with regard to those features in the predicate VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System (K052274), and with regard to the spot cautery element in the VasoView 6 Harvesting Cannula (K041981).
Device description	The VASOVIEW HEMOPRO 2 Endoscopic Vessel Harvesting System is designed for use in conjunction with the 7 mm Extended Length Endoscope. The Harvesting Cannula has four lumens which house the Endoscope, C-Ring, distal lens washer tube and VASOVIEW HEMOPRO 2 Harvesting Tool for the cutting and sealing of vessel branches. The Harvesting Tool has two curved Jaws. One of the Jaws contains the heating elements for branch cutting, sealing and spot cautery. An area near the tip of the convex side of the Jaw can be used for spot cautery. The Activation Toggle is used to control the Jaws to activate the heating elements. 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, VASOVIEW HEMOPRO 2 Extension Cable, and an Adapter Cable.

Indications for Use	The VASOVIEW HEMOPRO 2 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 fundamental scientific technology of the VASOVIEW HEMOPRO 2 Endoscopic Vessel Harvesting System is the same as that of the predicate VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System (cleared under K052274). The HEMOPRO 2 Endoscopic Vessel Harvesting System is designed to be used with the existing HEMOPRO Power Supply (a supply that converts commonly available AC to a specified DC) and the 7 mm Extended Length Endoscope for visualization. An Extension Cable connects the HEMOPRO 2 to an Adaptor Cable, which in turn attaches to the HEMOPRO Power Supply. The Harvesting Cannula holds the BTT (both cleared as part of the predicate HEMOPRO device), the Endoscope, Dissection Tip, and the Harvesting Tool. The BTT seals the tunnel to maintain insufflation and can supply CO2 for insufflation. The Endoscope allows for visualization and dissection. The Dissection Tip attaches to the distal end of the Endoscope to dissect the target vessel away from the surrounding tissue. The Harvesting Tool has two jaws which contain heating elements which cut and coagulate tissue like the predicate. A section of the jaws is constructed such that part of the heating element is revealed to create a spot cautery area. The heating elements (and thereby the spot cautery area) is activated by the actuation toggle on the handle of the tool. Technological changes from the HEMOPRO predicate include: redesigned circuitry in the handle that prevents false turn-on's, redesigned heating element to reduce cost and provide a spot cautery area, a new cable configuration and new connector type, more ergonomic handle, increased insulation of the jaws (preventing thermal spread), and improved cutting length.
Performance data	The results of verification and validation testing and Risk Analysis demonstrate that the VASOVIEW HEMOPRO 2 Endoscopic Vessel Harvesting System meets the established acceptance criteria and performs in a manner equivalent to the predicate devices. Bench testing and non-clinical validation testing were performed. Bench testing was done to verify and validate essential functional characteristics of the device. An example of this was thermal spread, i.e., the extent of necrosis beyond the length of the jaws. Non-clinical testing of the device in porcine models was done to validate that the device met user needs. In all cases the device met the acceptance criteria of the test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Maquet Cardiovascular, LLC
% Underwriters Laboratories, Inc.
Mr. Casey Conry
1285 Walt Whitman Road
Melville, NY 11747

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Re: K101274
Trade/Device Name: VASOVIEW HEMOPRO 2 Endoscopic Vessel Harvesting System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 5, 2010
Received: May 6, 2010

Dear Mr. Conry:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) number (if known)

The 510(k) number has not been issued yet.

Device name

VASOVIEW HEMOPRO 2 Endoscopic Vessel Harvesting System

Indications for Use

The VASOVIEW HEMOPRO 2 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 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.

Prescription Use __X__ (21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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