K140603

JUL 31 2014

Section 005

510(k) Summary (21 CFR § 807.92(c))

Submitter: Saphena Medical, Inc.
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West Bridgewater, MA 02379

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Date Summary Prepared: January 30, 2014

Device Trade Name: OnePass™ Endoscopic Vessel Harvesting System

Common Name: Electrosurgical cutting and coagulation device and accessories

Classification Name: Electrosurgical cutting and coagulation device and accessories

Product Code: GEI

Class II 21 CFR 878.4400

Predicate Devices: Maquet Cardiovascular, LLC Vasoview 6 Pro Endoscopic Harvesting System (K091733)
Decision Date: August 28, 2009

Device Description:

The OnePass™ Endoscopic Vessel Harvesting Systemattaches to existing laparoscopic endoscopes (e.g. 7mm) to provide a means to endoscopically harvest vessels for use in arterial bypass graft procedures. Endoscopic Vessel Harvesting is a procedure that has been in use for approximately 15 years. The OnePass™ device differs in that it provides for single device entry into the body cavity without the need for additional instruments. Also, the distal end effector design allows for excellent visibility and quick thermal ligation of vessel trunks while minimizing trauma to the target vessel.

Intended Use:

The Saphena Medical OnePass Endoscopic Vessel Harvesting 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 extra peritoneal or subcutaneous extremity and thoracic

space. Extremity procedures include tissue dissection 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. Thorascopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels, and other tissues of the chest wall.

Non-Clinical Performance Data:

The OnePass™ device performance characteristics were evaluated in the following studies:

- Design Verification Testing (including dimensional verification, tensile/compressive strength and durability)
- Compatibility Testing with standard 7mm scope
- Compatibility Electrical Safety and Electromagnetic Testing
- Packaging and Shipping Testing
- Sterility Testing
- Biocompatibility Testing
- Simulated animal testing use evaluation

Performance testing demonstrates that the device is as safe and effective and performs at least as safely and effectively as the predicate device stated in this summary.

Statement of Equivalence:

The OnePass™ Endoscopic Vessel Harvesting System is substantially equivalent to the Maquet Cardiovascular, LLC VasoView 6 Pro Endoscopic Harvesting System (K091733) decision date of August 8, 2009. As described in this submission, the intended use of the OnePass™ Endoscopic Vessel Harvesting System is equal to the predicate device. Further, the subject and predicate device have similar technological characteristics. The OnePass™ Endoscopic Vessel Harvesting System is equivalent to the predicate device in terms of intended use, principles of operations, technology, design, materials and performance. The noted difference between the OnePass™ Endoscopic Vessel Harvesting and predicate device does not raise new issues of safety or effectiveness.Laboratory studies have been performed to assess the safety and effectiveness of the new characteristics. The testing performed in support of this 510(k) submission was conducted in accordance with accepted scientific methods, including compliance with ISO 60601-1 3rd addition (Electrical Safety Testing for Medical Devices). Guidance documents and standards were followed as appropriate.

Summary:

Non-clinical testing of the subject device has shown that it meets its functional specification and performs according to the prescribed intended use. The OnePass™ Endoscopic Vessel Harvesting System is substantially equivalent to the predicate device in terms of its intended use, performance characteristics and product labeling. Based on the product technical information provided in this premarket notification, the OnePass™ Endoscopic Vessel Harvesting System has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 31, 2014

Saphena Medical Incorporated
Ms. Cheryl Blake
Regulatory Affairs/Quality Assurance, Saphena Medical Consultant
375 West Street
West Bridgewater, Massachusetts 02379

Re: K140603
Trade/Device Name: OnePass 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: July 8, 2014
Received: July 9, 2014

Dear Ms. Blake:

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" (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 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)*
K140603

Device Name
OnePass Endoscopic Vessel Harvesting System

Indications for Use *(Describe)*

The Saphena Medical OnePass Endoscopic Vessel Harvesting 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 extra peritoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection 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. Thorascopic 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

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