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

October 31, 2014

Terumo Cardiovascular Systems Corporation
Mr. Garry Courtney, MBA, RAC
Director, Regulatory Affairs
125 Blue Ball Road
Elkton, Maryland 21921

Re: K140008
Trade/Device Name: VirtuoSaph® Plus 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: September 29, 2014
Received: September 30, 2014

Dear Mr. Courtney:

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

TERUMO
Cardiovascular Systems

SECTION 4 – INDICATION FOR USE
VirtuoSaph® Plus Endoscopic Vessel Harvesting System

510(k) Number (if known): Unknown at time of submission K140008

Device Name: VirtuoSaph® Plus Endoscopic Vessel Harvesting System

Indications for Use:
The VirtuoSaph® Plus 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 and dissection of blood vessels of the extremities. Extremity procedures include tissue dissection and/or vessel harvesting along the saphenous vein for coronary artery bypass grafting and peripheral artery bypass grafting or radial artery for use in coronary artery bypass grafting.

Prescription Use (Part 21 CFR 801 Subpart D) ____X____ or Over-The-Counter Use (Part 21 CFR 807 Subpart C) _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

TERUMO
Cardiovascular Systems

SECTION 5 – 510(K) SUMMARY
VirtuoSaph® Plus Endoscopic Vessel Harvesting System

Date Prepared:	December 20, 2013
Sponsor Information:	
Owner/Applicant/Submitter:	Terumo Cardiovascular Systems Corporation 125 Blue Ball Road Elkton, MD 21921 Phone: 1-800-262-3304, Ext. 7486 Fax: 410-398-6079 Registration No. 1124841
Contact Person:	Garry A. Courtney, MBA, RAC Director, Regulatory Affairs Phone: 1-800-262-3304, Ext. 7486 Fax: 410-398-6079 Email: garry.courtney@terumomedical.com
Device Names/Classifications:	
Device Trade Name:	VirtuoSaph® Plus Endoscopic Vessel Harvesting System
Device Common Name:	Electrosurgical Cutting and Coagulation Device
Classification Name:	Electrosurgical Cutting and Coagulation Device
Regulation Number:	21 C.F.R. 878.4400
Classification:	Class II
Product Code:	GEI

Predicate Devices:

- Terumo VirtuoSaph® Plus Endoscopic Vessel Harvesting System – Cleared by FDA under K092789 on May 12, 2010.
- Guidant VasoView® 6 Endoscopic Vessel Harvesting System – Cleared by FDA under K041981 on August 20, 2004

Purpose of Submission:

Terumo Cardiovascular Systems Corporation is submitting this Premarket Notification because of its intent to expand the product's current usage indications. The expanded indication will allow for the device to be used in harvesting the radial artery for coronary artery bypass grafting procedures.

TERUMO
Cardiovascular Systems

Summary of Comparisons Between Subject and Predicate Devices:
This 510k Summary is intended to provide a brief presentation of the similarities and differences between the proposed VirtuoSaph® Plus device and the predicate VasoView® 6 device. This summary will include a review of product indications, technology, design, materials and product performance.

Intended Use/Indications for Use:
The subject VirtuoSaph® device shares common indications with the predicate VasoView® 6 device:

> ***Proposed VirtuoSaph® Plus Indications***:
> The VirtuoSaph® Plus is currently 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 and dissection of blood vessels of the extremities. The extremity procedures include tissue dissection and/or vessel harvesting along the saphenous vein for coronary artery bypass grafting and peripheral artery bypass grafting.
>
> ***Predicate VasoView® 6 Indications:***
> The VasoView® 6 device is FDA-cleared for use in minimally invasive surgery allowing for access to vessel harvesting, and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. It is also indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including the dissection of blood vessels and blood vessels of the extremities, dissection of ducts and other structures in the extraperitoneal or subcutaneous extremity and thoracic space. These extremity procedures include tissue dissection and vein harvesting along the saphenous vein (for use in coronary and peripheral artery bypass procedures), as well as harvesting of the radial artery for use in coronary artery bypass grafting. Additionally, thoroscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.

A primary difference between these two product indications is that the predicate VasoView® 6 device is cleared for the harvesting of the radial artery for use in coronary artery bypass grafting. It is Terumo Cardiovascular System's intent to expand its product indications to include harvesting of the radial artery for use in coronary artery bypass grafting. No additional product indications are being pursued with this submission.

TERUMO
Cardiovascular Systems

The proposed product indications for the VirtuoSaph® Plus Endoscopic Vessel Harvesting System are:

> The VirtuoSaph® Plus 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 and dissection of blood vessels of the extremities. Extremity procedures include tissue dissection and/or vessel harvesting along the saphenous vein for coronary artery bypass grafting and peripheral artery bypass grafting or **radial artery for use in coronary artery bypass grafting.**

Product Technology:
The primary functions of most vessel harvesting systems include tissue cauterization and tissue dissection functions. This is also true for the VirtuoSaph® Plus device and the predicate VasoView® 6 device. The subject VirtuoSaph® Plus device and the predicate VasoView® 6 device each rely upon bipolar radio frequency (RF) energy to cauterize vessels that are to be harvested. For each of these two devices, the RF current is transmitted across two electrodes in order to effect the necessary cauterization/sealing of the tissue when the tissue is appropriately positioned between the two electrodes.

With respect to cutting of the tissue, the VirtuoSaph® Plus device relies upon bipolar RF energy to effect separation, whereas the cutting process with the predicate VasoView® 6 is achieved by a mechanical blade which slices through the tissue to effect separation. While this difference is recognized, Terumo Cardiovascular Systems conducted performance assessments to demonstrate equivalence to the identified predicate device.

Design:
The design of the VirtuoSaph® Plus device and the VasoView® 6 device are similar. Both devices are designed to harvest vessels from the human body that are deemed appropriate for subsequent use (i.e., bypass grafting). Both devices are designed to be used with an endoscope and both products are packaged without endoscope – as the endoscopes are commercially available separate from the vessel harvesting systems.

The VasoView® 6 device presents with a *dissector tip* that can be affixed to endoscope for tunnel dissection whereas the VirtuoSaph® Plus device presents a separate full-length dissector device (with integrated conical tip) which "houses" the endoscope during tunnel dissection. The difference being that the conical shaped tip is an attachment component with the VasoView® 6 device verses a fully assembled device with the subject VirtuoSaph® Plus device. There is no clinical relevance to this difference in tunnel dissection as either method safely and effectively accomplishes tunnel dissection.

TERUMO
Cardiovascular Systems

Both devices utilize upon bipolar RF energy to coagulate vessels/branches during the harvesting of the vessel. Additionally, both devices are presented with the necessary bipolar connector/cord that will interface with the bipolar outlets of compatible generators.

The VirtuoSaph® Plus device and the VasoView® 6 device each provide CO_2 insufflation to assist in the tunneling and harvesting of target vessels. Insufflation with the VirtuoSaph® device is accomplished from the distal position of the system tools for both dissection and harvesting procedures, whereas the VasoView® 6 device provides insufflation from the proximal handle position for the dissection procedure – and from the distal position of the harvester rod during the harvesting procedure. This difference is clinically insignificant as insufflation is sufficiently accomplished with either device without adversely impacting clinical outcome.

Materials:
The materials that are used in the construction of the VirtuoSaph® Plus device and the VasoView® 6 device vary from component to component. While there are differences among the materials of construction, these differences are not clinically relevant. Both devices have already been cleared by FDA with their respective materials of construction, and because the devices are being used in the manner for which they were cleared, there would be no issues of safety or effectiveness with respect to materials. Furthermore, the materials used in the construction of the VirtuoSaph® Plus have satisfied all applicable biocompatibility requirements. It is concluded that while difference in materials do exist, these differences are not clinically relevant.

Performance Evaluations:
Terumo Cardiovascular Systems conducted performance studies with the VirtuoSaph® Plus Endoscopic Vessel Harvesting System (with expanded radial harvest indication) – where a comparison was made to the predicate VasoView® 6 device. The studies were comparative in nature with the intent to demonstrate performance equivalence between the devices. The studies were also designed and conducted to ensure that the subject VirtuoSaph® device satisfies appropriate device performance specifications and to ensure that it satisfies customer needs. There are no appreciable differences between the subject devices and the predicate devices with respect to product performance – including harvesting of the radial artery.

Clinical studies involving patients are not necessary to demonstrate the safety and effectiveness of the subject devices. Performance assessments for safety and effectiveness were accomplished through animal studies, cadaver studies and bench evaluations. These studies assessed the following:

- Radial Artery Dissection and Harvesting
- Insufflation
- Cauterization
- Radial Artery Encapsulation (V-Keeper)
- Burst Pressure
- Spot Cauterization
- Sealing / Bleeding

TERUMO
Cardiovascular Systems

Additional Areas of Comparison:
The information presented in this section depicts other areas of focus for examining the similarities and differences between the VirtuoSaph® Plus Endoscopic Vessel Harvesting System and the predicate device.

- ***Duration of Use***:
  The VirtuoSaph® Plus Endoscopic Vessel Harvesting System and the predicate VasoView® 6 can each be used in procedures lasting up to 6 hours in duration.

- ***Comparison of Labeling***:
  The labeling that will be used for the VirtuoSaph® Plus Endoscopic Vessel Harvesting System (with radial artery harvest indication) is nearly identical to the labeling of the same device (VirtuoSaph® Plus) without the expanded product indication.

  Additionally, the labeling for the subject device is comparable to the labeling associated with the predicate VasoView® 6 device in that both labeling schemes satisfy the required elements for medical device labeling – including adequate directions for use, product indications, instructions, warnings/cautions, and contact information.

Conclusion:
The information and data included in the 510(k) notice demonstrate the Terumo VirtuoSaph® Plus Endoscopic Vessel Harvesting System is *substantially equivalent* to the predicate VasoView® 6 Endoscopic Vessel Harvesting System with respect to harvesting of the radial artery for use in bypass grafting.