



Food and Drug Administration
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April 21, 2016

Terumo Cardiovascular Systems Corporation
Tierra Brown
Regulatory Affairs Specialist
125 Blue Ball Road
Elkton, Maryland 21921

Re: K160206

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: January 25, 2016
Received: January 28, 2016

Dear Tierra Brown:

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

Indications for Use

510(k) Number (if known)

K160206

Device Name

The VirtuoSaph® Plus Endoscopic Vessel Harvesting System

Indications for Use (Describe)

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.

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SECTION 5 – 510(k) Summary
VirtuoSaph® Plus Endoscopic Vessel Harvesting System

Date Prepared: January 25, 2016

Sponsor Information:

Owner/Applicant/Submitter: Terumo Cardiovascular Systems Corporation
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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 CFR 878.4400

Classification: Class II

Product Code: GEI

Predicate Device:

Terumo Cardiovascular Systems identifies the following device as a predicate article for this application:

- Terumo VirtuoSaph® Plus Endoscopic Vessel Harvesting System – Cleared by FDA under K140008 on October 31, 2014

Purpose of Submission:

Terumo Cardiovascular Systems Corporation is submitting this Traditional 510(k) Premarket Notification because of its intent to expand the product indications. Terumo seeks to expand the list of generators that can be used with the VirtuoSaph® Plus Endoscopic Vessel Harvesting System.



SECTION 5 – 510(k) Summary
VirtuoSaph® Plus Endoscopic Vessel Harvesting System

Substantial Equivalence Statement:

The device submitted in this 510(k) maintains characteristics that are substantially equivalent in intended use, design, technology/principles of operation, materials and specifications to the predicate device.

Summary of Comparisons Between Subject and Predicate Devices:

This 510(k) Summary is intended to provide a brief presentation of the similarities and differences between the subject VirtuoSaph® Plus device and the predicate VirtuoSaph® Plus device. This summary will include a review of product indications, technology, design, materials and product performance.

Intended Use/Indications for Use:

The subject VirtuoSaph® Plus device and the predicate VirtuoSaph® Plus device shares common indications.

Subject VirtuoSaph® Plus Indications:

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.

The subject VirtuoSaph® Plus device's instructions for use (IFU) will expand the list of generators deemed compatible for use with the device. Terumo intends to expand this list to include four additional generators. The description section of the IFU will list a total of seven generators deemed compatible for use with the VirtuoSaph® Plus Endoscopic Vessel Harvesting System. The full list of compatible generators will read:

Generator	Model	Foot Pedal Type	Mode	Setting Range (watts)
Olympus	UES-40	Dual (cut/coagulate)	Bipolar Cut	8-12
ValleyLab	Force FX	Single	Bipolar Macro	14-18
ValleyLab	Force FX-C	Single	Bipolar Macro	14-18
Bovie	Aaron OR/PRO 300	Single	Bipolar Macro	8-10
ConMed	System 5000	Single	Bipolar Macro	6-8
Olympus	ESG-400	Dual (cut/coagulate)	Bipolar BiSoftCoag Effect 3	8
Covidien	ForceTriad	Single	Bipolar Macro	6-7



SECTION 5 – 510(k) Summary
VirtuoSaph® Plus Endoscopic Vessel Harvesting System

Predicate VirtuoSaph® Plus Indications:

The predicate VirtuoSaph® Plus device has the same intended use/indications for use as the subject VirtuoSaph® Plus device's, with the expectation that the predicate device is currently cleared for use with three generators. The current generators that are deemed compatible for use are as follows:

Generator	Model	Foot Pedal Type	Mode	Setting Range (watts)
Olympus	UES-40	Dual (cut/coagulate)	Bipolar Cut	8-12
ValleyLab	Force FX	Single	Bipolar Macro	14-18
ValleyLab	Force FX-C	Single	Bipolar Macro	14-18

NOTE: The generators that are deemed compatible for use with the VirtuoSaph® Plus Endoscopic Vessel Harvesting System are not manufactured nor sold by Terumo Cardiovascular Systems Corporation.

Principles of Operation and Technology:

The subject VirtuoSaph® Plus device and the predicate VirtuoSaph® Plus device are both endoscopic vessel harvesting systems that rely upon bipolar radio frequency (RF) energy to cauterize and seal vessels that are to be harvested. With both the subject and the predicate 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, both devices relies upon bipolar RF energy to effect separation. The use of the new generators does not, in any way, change or alter the operation or technology of the VirtuoSaph® Plus Endoscopic Vessel Harvesting System.

Design and Materials:

The **design** of the subject VirtuoSaph® Plus device and the predicate VirtuoSaph® Plus device are the same. 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 an endoscope – as the endoscopes are commercially available separate from the vessel harvesting devices. The disposable endoscope is considered a component of the “System” and is subject to this application.

The **materials** that are used in the construction of the subject VirtuoSaph® Plus device and the predicate VirtuoSaph® Plus device are the same. The materials used in the construction of both VirtuoSaph® Plus devices have satisfied all applicable biocompatibility requirements.

Performance Evaluations:

Terumo Cardiovascular Systems conducted performance studies with each of the four additional generators that can be used with the VirtuoSaph® Plus System. The studies were comparative in nature with the intent to demonstrate performance safe and effective



SECTION 5 – 510(k) Summary
VirtuoSaph® Plus Endoscopic Vessel Harvesting System

use of the new generators. The studies were also designed and conducted to ensure that the proposed generators each satisfy appropriate device performance specifications, and to ensure that customer requirements are met. There are no appreciable differences between the performance of the VirtuoSaph® Plus System when used with the new generators versus performance when used with the existing generators.

Clinical studies involving patients are not necessary to demonstrate substantial equivalence of the subject VirtuoSaph® Plus System when used with the new generators. Substantial equivalence is demonstrated with the following *in-vitro* performance evaluations:

- Vessel Burst Testing
- Spot Cautery Testing
- Sealing / Hemostasis

Components of the VirtuoSaph® Plus Endoscopic Vessel Harvesting System:

- Trocar
- Dissector Rod
- Harvester Rod
- Endoscope (reusable device packaged separately)

Additional Areas of Comparison:

The information presented in this section depicts other areas of focus for examining the similarities and differences between the subject VirtuoSaph® Plus device's generators and the predicate VirtuoSaph® Plus device's generators.

- ***Duration of Use:***
The subject VirtuoSaph® Plus device and the predicate VirtuoSaph® Plus device can each be used in procedures lasting up to 6 hours in duration.
- ***Comparison of Labeling:***
The labeling that will be used for the subject VirtuoSaph® Plus device is identical to the labeling of the predicate VirtuoSaph® Plus device, except the Instructions for Use will be updated to include the use of the additional generators.

Conclusion:

The information and data included in this Traditional 510(k) Premarket Notification demonstrates the subject VirtuoSaph® Plus System's performance, when used with the new generators, is *substantially equivalent* to the performance when the VirtuoSaph® Plus System is used with the existing generators.