K092785

5. 510(k) Summary

MAY 12 2010

Type of 510(k) Submission:	Traditional
Device's Classification Name:	Electrosurgical Cutting and Coagulation Device
510(k) Submitter:	Terumo Cardiovascular Systems Corporation 6200 Jackson Road, Ann Arbor, MI 48103
Primary Contact Name:	Christina Thomas, Regulatory Affairs Manager Tel: (734)741-6278
Secondary Contact Name:	Steven Arick, Regulatory Affairs Director Tel: (734)741-6238
Date Prepared:	September 4, 2009
Device Trade name:	VirtuoSaph™ Plus Endoscopic Vessel Harvesting System
Device Common Name:	Electrosurgical cutting and coagulation device and accessories
Establishment Registration Number:	1828100
Classification:	Class II
Product Code:	GCJ
Panel:	79, General and Plastic Surgery Devices
Indication 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.

Description of the Device:	The system consists of a disposable trocar, dissector, and harvester. The trocar is inserted into the leg incision and stays in place with the clip securely placed on the skin allowing fast conversion between procedural steps. The dissector or harvester rod accesses the saphenous vein by entering the trocar through the port. A reusable endoscope (which is not in the scope of this submission) enters the body through dissector or harvester, and has optical components that send an image from inside of the body to a video monitor for the clinician to view. Dissector rod dissects the saphenous vein and surrounding branches. Harvester cauterizes and cuts the branches of the saphenous vein allowing for the harvesting of it.
Predicate Device:	VirtuoSaph™ Endoscopic Vein Harvesting System (K083194) Guidant VasoView 6 Harvesting Cannula (K041981)
Technological Characteristics:	The VirtuoSaph™ Plus Endoscopic Vessel Harvesting System incorporates the same fundamental scientific technology as both the predicate device # 1, VirtuoSaph™ Endoscopic Vein Harvesting System and predicate device # 2, Guidant VasoView 6 Harvesting Cannula (K041981).
Summary of substantial equivalence:	The VirtuoSaph™ Plus Endoscopic Vessel Harvesting System is substantially equivalent to both predicate devices in terms of intended use, principles of operation, technology, design, materials, and performance. Any noted differences between the devices are minor and do not raise new issues of safety and effectiveness.

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

Terumo Cardiovascular Systems Corporation
% Ms. Christina Thomas
6200 Jackson Road
Ann Arbor, Michigan 48103

MAY 12 2010

Re: K092789
Trade/Device Name: VirtuoSaph™ Plus Endoscopic Vessel Harvesting System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: May 10, 2010
Received: May 11, 2010

Dear Ms. Thomas:

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

4. Indication for Use Statement

Indications for Use

510(k) Number (if known): K092789

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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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

510(k) Number K092789