5. 510(k) Summary

JAN 16 2009

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:	Junko Kurosawa, Senior Associate, Regulatory Affairs Tel 1(800)262-3304, Extension 6563
Secondary Contact Name.	Christina Thomas, Manager, Regulatory Affairs Tel 1(800)262-3304, Extension 6278
Date Prepared:	October 28, 2008
Device Trade name:	VirtuoSaph™ Endoscopic Vein Harvesting Disposable System
Establishment Registration Number:	1828100
Classification:	Class II
Product Code	GCJ
Panel:	79, General and Plastic Surgery Devices
Indication for Use:	VirtuoSaph™ Endoscopic Vein Harvesting System has applications in minimally invasive surgery allowing access for endoscopic saphenous vein harvesting including tissue dissection for use in peripheral and coronary 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 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 Disposable System (K031891)
Purpose of the Submission:	Modification of the indication for use statement to include the word "peripheral" as a method of use

Technological Characteristics and Comparison to Predicate Device:

The difference between the modified and (unmodified) predicate device is only in the intended use statement It the addition of the word "peripheral" to the indications statement that relates only to a method of use, not to the effect of which harvesting is achieved

Conclusion:	In summary, the VirtuoSaph™ Endoscopic Vein Harvesting System with the modified indications for use statement is substantially equivalent in intended use, principles of operation, technology, design, materials, and performance to the predicate VirtuoSaph™ Endoscopic Vein Harvesting System Any noted differences between the devices do not raise new issues of safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2009

Terumo Cardiovascular Systems
% Junko Kurosawa
Regulatory Affairs
6200 Jackson Road
Ann Arbor, Michigan 48103

Re K083194
Trade/Device Name VirtuoSaph™ Endoscopic Vein Harvesting Disposable System
Regulation Number 21 CFR 876 1500
Regulation Name Endoscope and accessories
Regulatory Class II
Product Code GCJ
Dated January 5, 2009
Received January 7, 2009

Dear Junko Kurosawa

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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), 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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 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 (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson

Mark N Melkerson
Director
Division of General, Restorative
and Neurological 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) K083194

Device Name

VirtuoSaph™ Endoscopic Vein Harvesting Disposable System

Indications for Use

VirtuoSaph™ Endoscopic Vein Harvesting System has applications in minimally invasive surgery allowing access for endoscopic saphenous vein harvesting including tissue dissection for use in peripheral and coronary 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)

David Krause for WXM 1/16/2009

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083194