JUL 2 9 2003

K031891
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10.0 510(k) SUMMARY

Date of Application:	05 May 03
Applicant's Name and Address:	Terumo Cardiovascular Systems Corporation 6200 Jackson Road Ann Arbor, MI 48103
Name of Contact Person:	Kim E. Aves Sr. Regulatory Affairs Specialist
Telephone and Fax Numbers:	Telephone: (734) 741-6341 Fax: (734) 741-6030
Proprietary Name:	VirtuoSaph
Common Name:	Minimally Invasive Saphenous Vein Harvesting System
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories.
Classification Number:	878.4400
Class:	II
Classification Panel:	79, General and Plastic Surgery
Product Code:	GEI
Predicate Device:	Vaso-View™ Dissection / Vessel Harvesting System #K981700 Olympus Endoscopic System for Vessel Harvesting (endoscope only) #K963184
Applicability of Performance Standards:	Terumo has determined that no mandatory performance standards have been established for these devices under Section 514 of the Medical Device Amendments to Federal Food, drug, and Cosmetic Act or by any subsequent regulatory action.

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Device Intended Use:

The TCVS VirtuoSaph™ Endoscopic Vein Harvesting Disposable System has applications in minimally invasive surgery allowing access for endoscopic saphenous vein harvesting (commonly known as EVH) including tissue dissection and vessel harvesting along the saphenous vein for use in coronary artery bypass grafting.

Device Description:

The VirtuoSaph *System* is composed of a *Trocar*, two rods: the *Dissector Rod* (to dissect the saphenous vein (SV) and tributaries), and the *Harvesting Rod* (to transect and cauterize the branches and allow harvesting of the SV).

Summary of Comparative Technological Characteristics with Predicate Device:

- Intended use
- System Components
- Target patient population
- Two-Rod system
- CO_2 delivery
- Sterilization method

See Section 9.0.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 2003

Terumo Cardiovascular Systems Corporation
c/o Mr. Heinz Joerg Steneberg
Division Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
Newtown, Connecticut 06470

Re: K031891
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: July 11, 2003
Received: July 14, 2003

Dear Mr. Steneberg:

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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

K031891

510(k) Number (if known): Unknown

Device Name: VirtuoSaph™ Endoscopic Vein Harvesting Disposable System

Indications for Use:

The TCVS VirtuoSaph™ Endoscopic Vein Harvesting Disposable System has applications in minimally invasive surgery allowing access for endoscopic saphenous vein harvesting (commonly known as EVH) including tissue dissection and vessel harvesting along the saphenous vein for use in coronary artery bypass grafting.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

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

510(k) Number K031891