TERUMO

TERUMO CARDIOVASCULAR SYSTEMS CORPORATION

1C022947

MAR 2 0 2003

15 510(k) SMDA Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) Number is _____.

Submitter's Name:	Terumo Cardiovascular Systems Corporation
Submitter's Address:	6200 Jackson Road, Ann Arbor, Michigan 48103-9300
Contact Person:	Mark A. Bur
Phone Number:	(734) 741-6117
FAX Number:	(734) 663-5062
Summary Date:	July 31, 2002

Device Trade Name:
Terumo® Advanced Perfusion System 1

Device Classification Name:
Cardiopulmonary bypass heart-lung machine (21 CFR 870.4220)

Predicate Devices:
Sarns™9000 Heart-Lung Console (K871131)
Sarns™ 8000 Modular Perfusion System (K915183)
Sarns™ 8000 Roller Pump (K953901)
Sarns™ 9000 Universal Roller Pump (K953904)
Flow Sensor Centrifugal Control Module (K950739)
Delphin II/Stand-Alone Centrifugal Module (K935978)

Indication for Use
The Terumo® Advanced Perfusion System 1 is indicated for up to 6 hours of use in extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures only, and intended to be used by a qualified perfusionist who is experienced in the operation of Sarns™ brand or similar equipment.

Device Description:
The Terumo® Advanced Perfusion System 1 is a highly configurable system with a distributed network architecture that allows the user to customize the number and types of system components, which can then be configured, displayed, and controlled from a central monitor. Within reason, the system should allow users to define and configure a system to meet their individual requirements, and as needed, adapt the configuration as their needs change. The basic Terumo® Advanced Perfusion System 1 consists of a Chassis platform which provides operating power and battery back-up power for all other devices of the system that enable, facilitate or improve the intended use of the product and integrated functions, the Central Control Monitor which through its software and display touch screen facilitates the configuration and control of all other components, the Air Bubble Detect Module which is used to detect gross air bubbles in the arterial line of the perfusion circuit with the Terumo® Air Sensor, and the Level Detect Module which is used to monitor blood levels within a hard shell reservoir with the Terumo® Level Sensors. The following modules may also be used to enhance the abilities of the Terumo® Advanced Perfusion System 1: Temperature Module, Pressure Module, Flowmeter Module, Occluder Module, RS-232 Interface Module, RS-485 Interface Module, CDI™ 100 Interface Module, CDI™ 500 Interface Module, 6" diamter race Roller Pump, 4" diameter race Roller Pump, Centrifugal Control Module, and a 33" or 15" Lamp. This design allows perfusionists to select the number and types of the

accessory devices needed to control and monitor patient perfusion during cardiopulmonary bypass.

Technological Characteristics:
The Terumo® Advanced Perfusion System 1 is a combination of the technologies from the current legally marketed devices, Sarns™ 8000 Modular Perfusion System, Sarns™9000 Heart-Lung Console, Sarns™ 8000 Roller Pump, Sarns™ 9000 Universal Roller Pump, Flow Sensor Centrifugal Control Module, and Delphin II/Stand-Alone Centrifugal Module and present day technology for computer controlled systems. The main differences between the predicate devices, Sarns™ 8000 Modular Perfusion System, Sarns™9000 Heart-Lung Console, and Delphin II/Stand-Alone Centrifugal Module, and the Terumo® Advanced Perfusion System 1 are:

- individual modules applications compared to the subsystem modules in the 8000 system,
- enhanced parameter entry for all modules via the Central Control Monitor compared to the minimal parameter user entry of the 9000 system via its touch screen,
- ability to control Electronic Gas Blender, Roller Pumps, and Centrifugal Control Module of the system via the Central Control Monitor or individual module controls compared to the individual controls required of the 8000, 9000, and Delphin stand-alone system,
- ability to setup multiple case configurations parameters on the Central Control Monitor software and recall the configuration parameters for use in a future cases compared to only one past systems setup and parameter setup each time,
- ability to configure a multi-module system for use of the users choice desired components rather than be constricted to only the few components available and the manufacturers platform layout on past systems.

Non-clinical Performance:
The performance characteristics of the Terumo® Advanced Perfusion System 1 were exhaustively tested and compared with the performance characteristics of the currently marketed Sarns™ 8000 Modular Perfusion System, Sarns™9000 Heart-Lung Console, Sarns™ 8000 Roller Pump, Sarns™ 9000 Universal Roller Pump, Flow Sensor Centrifugal Control Module, and Delphin II/Stand-Alone Centrifugal Module. All new and existing performance characteristics of the Terumo® Advanced Perfusion System 1 have been validated.

Conclusion from Conducted Testing:
The Terumo® Advanced Perfusion System 1 perform as intended according to its performance specifications. The Terumo® Advanced Perfusion System 1 is substantially equivalent to its predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

Terumo Cardiovascular Systems Corporation
c/o Mr. Mark A. Bur
6200 Jackson Road
Ann Arbor, MI 48103-9300

Re: K022947
Advance Perfusion System 1
Regulation Number: 21 CFR 870.4220
Regulation Name: CPB Heart Lung Machine Console
Regulatory Class: Class II (two)
Product Code: DTQ
Dated: December 20, 2002
Received: December 23, 2002

Dear Mr. Bur:

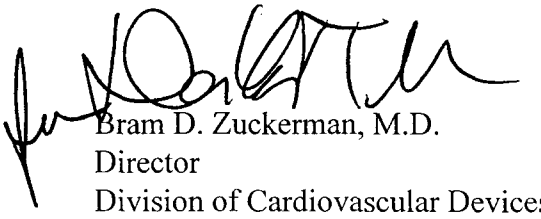
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022947

Device Name: Terumo® Advanced Perfusion System 1

Indications For Use:

The Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

The centrifugal pump is indicated for use in cardiopulmonary bypass procedures only.

Mark A. Bur
Regulatory Affairs Specialist
Terumo Cardiovascular Systems

(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 Cardiovascular Devices

510(k) Number K022947

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)