K071521

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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

Submitters Name:	Terumo Cardiovascular Systems Corporation
Submitters 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:	May 30, 2007

Device Trade Name:
Terumo® HX2™ Temperature Management System

Common Name:
Temperature Management System (TMS)

Device Classification Name:
Cardiopulmonary Bypass Temperature Controller (21 CFR 870.4250)

Legally Marketed Predicate Device:
Sarns™ Dual Cooler/Heater (Preamendment)
Sarns™ Temperature Control and Monitor System (TCM II) (K883603)

Indications for Use:
The Terumo® HX2™ Temperature Management System is indicated for use to supply temperature regulated water to heat exchangers during open heart surgery.

Operation	10° to 40°C, less than 75% relative humidity, non condensing
Storage	Ventilated area, -30° to 54° C (-22 to130°F), less than 95% relative humidity, non-condensing.
Transporting	Units may be transported up or down an incline up to 15 degrees without tipping.

Device Description:
The Terumo® HX2™ Temperature Management System provides temperature control of two independent water circuits that directly control the temperature of patient blood and cardioplegia solution during cardiovascular bypass surgery.

The system consists of a water tank, circulating pumps, heater manifolds, mercury free temperature sensors, water detectors, mixing valves and a tank divider which is provided to partition the tank into two separate channels (Left and Right).

The system will have the capacity to circulate water at least 6.5 gal/min (25 L/min) with no load connected.

The system is capable of heating and cooling for a single channel or for both channels.

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Channels are configurable such that different water/ice mixture ratios can be obtained. Manually added ice is the only means of obtaining the cool water supply. If a channel should fail during use, the user may switch the water hose connections to the other channel allowing the user to be operational in less than or equal to a minute.

Software is used to adjust and display channel set temperatures, acquire and display actual temperatures, automatically regulate temperatures to the entered setpoint, perform system diagnostics, and present visual and audible indications of faults that may occur.

Technological Characteristics:

The Terumo® HX2™ Temperature Management System is a combination of the technologies from the current legally marked devices, Sarns™ Dual Cooler/Heater and the Sarns™ Temperature Control and Monitor System (TCM II) and the present day technologies and a computer. The main differences between the predicate devices, Sarns™ Dual Cooler/Heater and the Sarns™ Temperature Control and Monitor System (TCM II) and the Terumo® HX2™ Temperature Management System are:

- old Hg-added switches used in predicates replaced with thermosistors and rtd temperature sensors,
- old single channel of Dual Cooler Heater and 2 dependent channels of TCM II compared to 2 independent channels with equal capability,
- automated control of the new system for both heating and cooling compared to predicates manual control,
- improvements to the priming and draining of the new system compared to both predicates,
- range of user temperature setpoints for both channels compared to predicate (4) hardware limited setpoints,
- new system diagnostics will display error codes compared to no indications for the Dual Cooler Heater and only LED visual indicators on the TCM II,
- temperature display accuracy better than analog temperature display on Dual Cooler Heater.

Non-clinical Performance:
The performance characteristics of the Terumo® HX2™ Temperature Management System were exhaustively tested and compared with the performance characteristics of the currently marketed Sarns™ Dual Cooler/Heater and the Sarns™ Temperature Control and Monitor System (TCM II). All new and existing performance characteristics of the Terumo® HX2™ Temperature Management System have been validated.

Conclusion from Conducted Testing:
The Terumo® HX2™ Temperature Management System performed as intended according to its performance specifications. The Terumo® HX2™ Temperature Management System is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2007

Terumo Cardiovascular Systems Corp.
c/o Mr. Mark A. Bur
6200 Jackson Rd.
Ann Arbor, MI 48103

Re: K071521
Terumo HX2 Temperature Management System
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary bypass temperature controller
Regulatory Class: Class II (two)
Product Code: DWC
Dated: November 8, 2007
Received: November 9, 2007

Dear Mr. Bur:

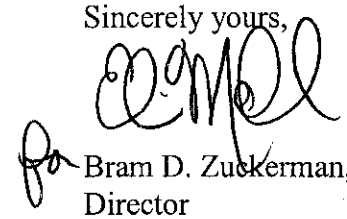
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K071521

Device Name: **Terumo® HX2™ Temperature Management System**

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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 Cardiovascular Devices

510(k) Number K071521