K 122813

510(k) Summary

1. COMPANY INFORMATION

DEC 1 8 2012

Cincinnati Sub-Zero Products, Inc.
12011 Mosteller Road
Cincinnati, Ohio 45241-1528
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2. CONTACT INFORMATION

Steve Berke
President and CEO
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3. DATE PREPARED: September 12, 2012

4. DEVICE TRADE NAME: Hemotherm® Model 400CE Cooler/Heater System and Blankets

5. COMMON NAME: Heater-Cooler temperature control device

6. CLASSIFICATION NAME: Cardiopulmonary bypass temperature controller

7. CLASSIFICATION REGULATION: 21 CFR 870.4250 for use with heat exchanger, 21CFR870.5900 for use with hypo-hyperthermia blanket

8. CLASSIFICATION PRODUCT CODE: DWC when used as cardiopulmonary bypass temperature controller, DWJ when used with a hypo-hyperthermia blanket

9. PANEL: Cardiovascular

10. DEVICE CLASSIFICATION: Class II

11. IDENTIFICATION OF PREDICATES:
    - K811742 Cincinnati Sub-Zero Hemotherm Model 400 Cooler/Heater System
    - K031544 Jostra HCU 30 Heater-Cooler Device
    - K101589 Cincinnati Sub-Zero Blanketrol III Model 233 and blankets

DEVICE DESCRIPTION

The Hemotherm® Model 400CE Cooler/Heater System is a dual reservoir, water re-circulating device that supplies temperature controlled water to a heat exchanger. The

device, in conjunction with a heat exchanger, is used to warm or cool the blood that enters and exits a blood heat exchanger for adult, pediatric or infant patients. The device uses conductive heat transfer. When ordered by the health care professional, the device can also simultaneously supply temperature controlled water to a blanket to provide additional patient re-warming therapy. If the blanket is used at the same time as the heat exchanger, the blanket is supplied the same water that circulates to the heat exchanger.

Water Cooling System Operation

Water is cooled to the desired set point temperature and pumped from the device to a commercially available heat exchanger via connecting hoses/tubes. The temperature controlled water is circulated through the heat exchanger to cool the blood in the heat exchanger and then the water is returned back to the Hemotherm. The Hemotherm device does not contact the patient or the patient's blood. The water being circulated by the Hemotherm is separated from the blood by the heat exchanger.

Water Heating System Operation

Water is heated to the desired set point temperature and pumped from the device to a commercially available heat exchanger via connecting hoses/tubes. The temperature controlled water is circulated through the heat exchanger to heat the blood in the heat exchanger and then the water is returned back to the Hemotherm. The Hemotherm device does not contact the patient or the patient's blood. The water being circulated by the Hemotherm is separated from the blood by the heat exchanger. If ordered by the health care professional, while in the heat mode, the Hemotherm may also be simultaneously connected to a blanket to provide additional patient re-warming therapy. The blanket is supplied the same water from the same reservoir as the heat exchanger, thus the blanket receives water of the same temperature as the heat exchanger.

INTENDED USE

The Hemotherm® Dual Reservoir Cooler/Heater is used to lower, maintain, or raise the temperature of the water flowing through a Blood Oxygenator/Heat Exchanger that is used to cool or warm blood during cardiopulmonary bypass procedures lasting six hours or less. The Hemotherm Dual Reservoir Cooler/Heater may also be used with a hyper/hypothermia blanket under the patient to provide warming through conductive heat transfer.

SUBSTANTIAL EQUIVALENCE

The new device has the same intended uses as the predicate devices and similar technological characteristics that do not raise new types of questions of safety and effectiveness thus meeting the definition of substantial equivalence. In addition, testing of the device shows that it meets applicable electrical safety and EMC standards. Temperature safety testing shows the device to meet the same requirements as the predicate.

COMPARISON TABLE

	Cincinnati Sub-Zero Hemotherm 400CE (New Device)	Cincinnati Sub-Zero Hemotherm 400 (K811742)	Jostra HCU 300 (K031544)	Cincinnati Sub-Zero Blanketrol III Model 233 with blankets (K101589)
Applications	Fluid cooling or warming using blood oxygenator/heat exchanger and additional warming with a blanket	Fluid cooling or warming using blood oxygenator/heat exchanger.	Total-body heating/cooling, independent cardioplegia (dual hyper-hypothermia system)	To raise or lower a patient's temperature or maintain a desired patient temperature
Patient Population	Adults, pediatrics, infants.	Adults and pediatrics	Adults and pediatrics.	Adults, pediatric, infants
Design	Heated or cooled water pumped through heat exchanger for conductive heat transfer	Heated or cooled water pumped through heat exchanger for conductive heat transfer	Heated or cooled water pumped through heat exchange circuits for conductive heat transfer to fluid	Heated or cooled water pumped through blankets for conductive heat transfer
Operating Mode	Manual mode (Water Temp)	Manual mode (Water Temp)	Manual mode (Water Temp)	Manual mode (Water Temp)
Temperature Range	3°C to 42°C.	3°C to 42°C.	1°C to 41°C.	4°C to 42°C
Energy	Conductive heat transfer.	Conductive heat transfer.	Conductive heat transfer.	Conductive heat transfer.

TESTING SUMMARY

The Hemotherm 400CE system was subjected to and passed:

- electrical safety testing in accordance with IEC60601-1,
- electromagnetic compatibility testing in accordance with IEC60601-1-2,
- package and transportation testing in accordance with ISTA standards
- performance testing in accordance with ASTM F-2196 (temperature and pressure).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DEC 18 2012

Cincinnati Sub-Zero
c/o Mr. Steven J. Berke
President and CEO
12011 Mosteller Road
Cincinnati, OH 45241-1528

Re: K122813
Hemotherm® Model 400CE Dual Reservoir Cooler/Heater System
Regulation Number: 21 CFR 870.4250
Regulation Name: Controller, Temperature, Cardiopulmonary Bypass
Regulatory Class: Class II
Product Code: DWC
Dated: November 8, 2012
Received: November 9, 2012

Dear Mr. Berke:

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,

Matthew G. Hillebrenner

for 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): K122813

Device Name: Hemotherm® Model 400CE Dual Reservoir Cooler/Heater

Indications for Use:

The Hemotherm® Dual Reservoir Cooler/Heater is used to lower, maintain, or raise the temperature of the water flowing through a Blood Oxygenator/Heat Exchanger that is used to cool or warm blood during cardiopulmonary bypass procedures lasting six hours or less. The Hemotherm Dual Reservoir Cooler/Heater may also be used with a hyper/hypothermia blanket under the patient to provide warming through conductive heat transfer.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices

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