510(k) Summary

1. COMPANY INFORMATION

   Cincinnati Sub-Zero Products, Inc.
   12011 Mosteller Road
   Cincinnati, Ohio 45241-1528
   Telephone: (513) 772-8810
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   Establishment Registration #: 1516825

2. CONTACT INFORMATION

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   President and CEO
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3. DATE PREPARED: January 10, 2011

4. DEVICE TRADE NAME: Blanketrol II Model 222S Hyper-Hypothermia System

5. COMMON NAME: Temperature management system

6. CLASSIFICATION NAME: System, Thermal Regulating

7. CLASSIFICATION REGULATION: 21 CFR 870.5900

8. CLASSIFICATION PRODUCT CODE: DWJ

9. PANEL: CARDIOVASCULAR

10. DEVICE CLASSIFICATION: Class II

11. IDENTIFICATION OF PREDICATES:
    a. Cincinnati Sub-Zero Blanketrol III Model 233 Hyper-Hypothermia Temperature Management System (K101589)

DEVICE DESCRIPTION

The Blanketrol II Model 222S is a water (liquid) recirculating device providing either hypothermia, hyperthermia or normothermia treatment as determined by the health care provider.

Water is either heated or cooled depending on the need of the patient. The heated or cooled water is pumped through connecting flexible tubing to a disposable or reusable

pad or blanket to provide patient therapy for a site specific external surface area or for whole body surface temperature therapy by the means of conductive heat transfer.

DESCRIPTION OF THE CHANGES TO THE DEVICE

The Blanketrol II Model 222S device is a modified, simpler, version of the Blanketrol III Model 233 (K101589). The following changes have been incorporated:

- Membrane control panel
  - The graphic appearance and color scheme of the membrane panel has been changed.
  - Three buttons and their corresponding functions that were available on the Blanketrol III Model 233 have been removed from the Blanketrol II Model 222S.
  - All other buttons, functions and construction remain the same without modification.
- Operation of the device
  - The Blanketrol II Model 222S does not offer a Gradient 10C mode, Gradient Variable mode and a Smart mode.
- No USB interface to an external computer
  - The USB port that is provided with the Blanketrol III Model 233 is not available with the Blanketrol II Model 222S.
- Labeling
  - The Operation and Technical Manual has been updated from the Blanketrol III Model 233 manual to reflect the above changes, including new name and model number.

The Blanketrol III Model 233 and the Blanketrol II Model 222S are the same device in all other aspects including intended use, operating principle, specifications, operation, software, and certification to IEC standards.

INTENDED USE

The Blanketrol II Model 222S Hyper-Hypothermia Temperature Management System is used to lower or to raise a patient's temperature and/or maintain a desired patient temperature through conductive heat transfer. The system is composed of a heater, a compressor, a circulating pump and blankets/pads.

VERIFICATION TESTING OF CHANGES

Testing was performed on the proposed Blanketrol II Model 222S in order to verify the changes in accordance with the company's specified design requirements, and to demonstrate the modified system is substantially equivalent to the predicate device.

Testing included:

- Function of the membrane control panel including button functionality.
- Device operation with the modified membrane panel including verification of water temperature and safety limits.

The modified system continues to meet the applicable requirements of the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

All necessary testing has been performed for the Blanketrol II Model 222S Hyper-Hypothermia Temperature Management System to assure substantial equivalence to the predicate device.

SUBSTANTIAL EQUIVALENCE

The modified device has the same intended use as the unmodified predicate and same technological characteristics that do not raise new types of questions of safety and effectiveness and is therefore substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

FEB - 4 2011

Re: K110104
Blanketrol II Model 222S Hyper-Hypothermia Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: January 10, 2011
Received: January 13, 2011

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,

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): K110104

Device Name: Blanketrol II Model 222S Hyper-Hypothermia Temperature Management System

Indications for Use:

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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)

(Division Sign-Off)
Division of Cardiovascular Devices

(Posted November 13, 2003)

510(k) Number K110104