

510(k) Summary

1. COMPANY INFORMATION

Cincinnati Sub-Zero, Inc.
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Cincinnati, Ohio 45241-1528
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SEP 20 2010

2. CONTACT INFORMATION

Steve J. Berke
President and CEO
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3. DATE PREPARED: June 4, 2010

4. DEVICE TRADE NAME: Blanketrol III Model 233 Hyper-Hypothermia System, CoolBlue Model 25-01 Hyper-Hypothermia System when sold by Innercool Therapies Inc.

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 Hyper-Hypothermia System, Model 200 (pre-amendment device)
- b. Gaymar Industries MediTherm II Series 5900 Hyper/Hypothermia System (K912051)
- c. M.T.R.E Advanced Technology Ltd. CritiCool device (K083662)

DEVICE DESCRIPTION

The Blanketrol III/CoolBlue Hyper-Hypothermia System 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.

INTENDED USE

The Blanketrol III Model 233 and CoolBlue Model 25-01 Hyper-Hypothermia Temperature Management Systems are 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.

BENCH TESTS PERFORMED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Bench testing was performed in order to validate the design according to the company's specified design requirements, and to demonstrate the new systems are substantially equivalent to the predicate devices.

The following bench tests were performed:

- Temperature Performance Testing
- System Safety Limit Testing (high and low limits)
- Transportation Testing
- Blanket Structural Integrity Testing

In addition, the new systems 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 III and CoolBlue Hyper-Hypothermia Temperature Management Systems to assure substantial equivalence to the predicate devices.

SUBSTANTIAL EQUIVALENCE

The new devices have the same intended use as the predicates and similar technological characteristics that do not raise new types of questions of safety and effectiveness and are therefore substantially equivalent to the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

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

SEP 20 2010

Re: K101589
Blanketrol III Model 233 and CoolBlue Model 25-01 Hyper/Hypothermia
Systems
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: September 13, 2010
Received: September 15, 2010

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

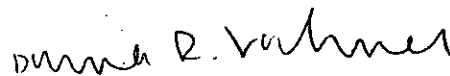
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


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

K101589

SEP 20 2010

510(k) Number (if known): K101589

Device Name: Blanketrol III Model 233 and CoolBlue Model 25-01 Hyper-Hypothermia Temperature Management Systems

Indications for Use:

The Blanketrol III Model 233 and CoolBlue Model 25-01 Hyper-Hypothermia Temperature Management Systems are 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.

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)

Dwight R. Valmer

(Division Sign-Off)
Division of Cardiovascular Devices

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(Posted November 13, 2003)