K120081

510(k) Summary

FEB 17 2012

1. COMPANY INFORMATION

Cincinnati Sub-Zero Products, Inc.
12011 Mosteller Road
Cincinnati, Ohio 45241-1528
Telephone: (513) 772-8810
FAX: (513) 772-9119

2. CONTACT INFORMATION

Steven J. Berke
President and CEO
Telephone: (513) 772-8810 ext 3212
FAX: (513) 772-9119
Email: sjberke@cszinc.com

3. DATE PREPARED: February 10, 2012

4. DEVICE TRADE NAME: Norm-O-Temp® Model 111Z Hyperthermia System including blankets/pads

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. Seabrook Medical Systems Mini-Temp Hyperthermia system including blankets (K881332)
    b. Cincinnati Sub-Zero Blanketrol III Model 233 Hyper-Hypothermia system including blankets/pads (K101589)
    c. SIMS Level 1 Snuggle Warm 4000/Equator 5000 Convective Warming system including blankets (now sold by Smiths Medical ASD) (K011907)

DEVICE DESCRIPTION

The Cincinnati Sub-Zero Norm-O-Temp (Model 111Z) is a water re-circulating system providing either hyperthermia or normothermia treatment as determined by the health care provider. It is a total body hyperthermia system used to keep a patient comfortable by maintaining blanket/pad water temperature through conductive heat transfer.

Water is heated and pumped from the device, through connecting flexible tubing, to disposable or reusable blankets/pads. The blankets/pads rest under, on top of and/or around the patient and are designed so that the water circulates through the blankets/pads and returns back to the device. The device is designed to operate based on the temperature of the circulating water.

The system is used in Operating rooms, Post Anesthesia Care Units, Recovery rooms, Intensive Care Units, and Emergency Rooms with adult, pediatric and infant (including neonate) patients.

The blankets/pads that are used with the Norm-O-Temp system are offered in a variety of sizes from large to small to meet the needs of the patients.

INTENDED USE

The Norm-O-Temp® Model 111Z hyperthermia system is intended to prevent hypothermia during surgical procedures and to reduce cold discomfort before, during, and after a surgical procedure. The thermal regulating system is used to keep a patient comfortable by maintaining blanket/pad water temperature through conductive heat transfer. The water heated blankets transfer the thermal energy to adult, pediatric, and infant (includes neonates) patients to keep a patient at a comfortable temperature. The Norm-O-Temp system is composed of a heater, circulating pump, and blankets/pads. It is intended for use by appropriately trained healthcare professionals in clinical environments.

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 system is substantially equivalent to the predicate devices.

The following bench tests were performed:

- Temperature Performance Testing (per ASTM F-2196)
- System Safety Limit Testing (per ASTM F-2196)
- Transportation Testing

In addition, the new system meets the applicable requirements of the following standards:

- IEC 60601-1 (Second Edition), Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- IEC 60601-1-2:2007 (Third Edition), Medical Electrical Equipment - Part 1-2: General Requirements for Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

Testing demonstrates substantial equivalence between the Norm-O-Temp system and predicate devices.

SUBSTANTIAL EQUIVALENCE

The new device is substantially equivalent to the predicate devices because it has the same intended use and has the same or similar technological characteristics that do not raise new types of questions of safety and effectiveness.

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

FEB 17 2012

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

Re: K120081
Norm-O-Temp® Model 111Z Hyperthermia Systems
Regulation Number: 21 CFR 870.5900
Regulation Name: System, Thermal Regulating
Regulatory Class: Class II
Product Code: DWJ
Dated: February 10, 2012
Received: February 13, 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,

M. J. Hildebrandt

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): K120081

Device Name: Norm-O-Temp® Model 111Z Hyperthermia 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)

(Posted November 13, 2003)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

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