K071918

510(k) SUMMARY

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

510(k) Summary of Safety and Effectiveness

Submitter Information

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NOV 0 9 2007

Date Summary Prepared: June 1, 2007 (Rev. A)

Device Information

ChillBuster® Model 8002 Portable Electric Blanket, with CDRH formal identity:

Device Group:	System, Thermal Regulating
Medical Specialty:	Cardiovascular
Product Code:	DWJ
Device Class:	2
Regulation No.:	870.5900

Predicate Devices

#K991684 ChillBuster® Model 8001 Portable Electric Blanket, CDRH formal identity:

Device Group:	System, Thermal Regulating
Medical Specialty:	Cardiovascular
Product Code:	DWJ
Device Class:	2
Regulation No.:	870.5900

#K952329 Life-Air 1000® Hypothermic Therapy System. Its CDRH formal identity is:

Device Group:	System, Thermal Regulating
Medical Specialty:	Cardiovascular
Product Code:	DWJ
Device Class:	2
Regulation No.:	870.5900

Device Description

The ChillBuster® Model 8002 Portable Electric Blanket System features a special electrical resistively heated Blanket, a Controller to manage power and device function, a rechargeable Battery, special cabling, and means to connect to external DC or AC power for recharging the Battery and, at the option of the user, operating the Blanket. During therapy, the Blanket is encased in a Sterile, Single-Use Blanket Cover to prevent cross-contamination of successive patients and to prevent soiling. The device can perform therapy at virtually any interval in the following activities or activity chains: a) initial patient preparation and transport in the field, and at any stage of ER, surgery, and ICU or post-op care for injury victims from the field; b) pre-op, surgery, ICU or post-op care of in-facility patients; and c) special situations involving potential or actual hypothermia (e.g. hemodialysis; peritoneal dialysis; plasmapheresis; patient warming during transport from point to point, etc.).

Intended Use

The ChillBuster® Model 8002 Portable Electric Blanket has been developed to reduce the effects of hypothermia encountered during the trauma of a surgical procedure or other medical crisis which could result in the onset of a hypothermic condition. This is the same as that of the ChillBuster® predicate and the Life-Air predicate.

For both the ChillBuster® proposed and predicate devices, use is limited to whole-body warming in adult humans, free of skin conditions or other impairments where distributed heat application is deemed contraindicated by the responsible physician. In turn, the Life-Air predicate can also treat younger and pediatric patients.

Technological Characteristics

The proposed device is largely the same as the ChillBuster® predicate device. The significant differences are that the proposed device can operate the Blanket while connected to the AC line, and the power output to the Blanket is higher in the proposed versus predicate device (but still low compared to the Life-Air Predicate), and the proposed device has improved Blanket temperature monitoring and assurance of even heat distribution.

Non-Clinical Performance Data

The proposed device has been tested to currently valid versions of the following Consensus Standards and other Standards that include:

IEC/EN 60601-1, General Medical Safety;
EN/IEC 60601-1-2, Electromagnetic Compatibility;
IEC 60601-2-35, Heating Pads and Blankets;
ISO 14971, Application of Risk Management to Medical Devices;
CAN/CSA C22.2 No. 601.1-M90, Canadian General Medical Safety.

The proposed device Blanket was subjected to 50 washing/drying cycles using household detergent and machines, with no sign of wear or deterioration, and function was demonstrated to be normal in the five sessions in which Blanket heating performance was tested. In separate tests, it was demonstrated that the Blanket functions normally even when completely submerged (except for the Blanket Connector that connects the Blanket to a cable from the Controller).

Analytical calculations were carried out to show that the heat density at the actively heated surface of the ChillBuster® proposed device Blanket was higher than that of the ChillBuster® predicate but only a small percentage of that of the actively heated surface of the Life-Air predicate patient cover. Importantly, the Life-Air predicate specifies a safety cutoff temperature of 43 ± 3°C, whereas the ChillBuster® proposed device Blanket limit is 41 ± 1°C. The latter is the same as that specified for maximum safety cutoff temperature in the International Standard IEC 60601-2-35.

Conclusion

The ChillBuster® proposed device is substantially equivalent to the ChillBuster® predicate device in terms of System general structure, arrangement, function, and temperature tolerance, and to the Life-Air Predicate device in terms of operation from the AC line, temperature safety limits, and output power to the patient therapy component (blanket or cover). The proposed device and both predicates have the same basic Intended Use and Indications for Use. The Predicate 8001 and the proposed device place qualifications on patient age and condition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2007

ThermoGear Inc.
c/o Mr. Gregor Dzialas
Responsible Third Party Official
12 Commerce Road
Newtown, CT 06470

Re: K071918
ChillBuster® Model 8002 Portable Electric Blanket
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (Two)
Product Code: DWJ
Dated: July 10, 2007
Received: October 24, 2007

Dear Mr. Dzialas:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 devices, 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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): K071918

Device Name: *Chill*Buster® Model 8002 Portable Electric Blanket

Indications for Use: The *Chill*Buster® Model 8002 has been developed to reduce the effects of hypothermia encountered during the trauma of a surgical procedure or other medical crisis which could result in the onset of a hypothermic condition. Use is limited to whole-body warming in adult humans, free of skin conditions or other impairments where distributed heat application is deemed contraindicated by the responsible physician.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __ (Part 21 CFR 801 Subpart D)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071918