

K991684

MAR - 1 2000

APPENDIX III

510(k) Summary
(Reference: Section G, Main Text)

**The following material
presents the 510(k) Summary
for the ChillBuster® Model 8001
Portable Electric Blanket**

K 991684

ThermoGear, Inc.™

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Tigard, OR 97224
(503) 624-1415
(Fax) 624-2784

510(k) Summary

Submitter Information

ThermoGear™, Inc. (address and phone/fax numbers per letterhead)
Contact Person: Wayne Fields, Ph.D.
Summary Preparation Date: May 1, 1999

Device Information

Trade or Proprietary Name: ChillBuster® Model 8001 Portable Electric Blanket
Device Common or Usual Name: Hypothermic Therapy System
CDRH Product Nomenclature: Thermal Regulation System (21 CFR 870.5900)
Classification: 74 DWJ

Predicate Device

ThermoGear™ has designated the Life-Air 1000® Hypothermic Therapy System, manufactured by Progressive Dynamics Inc. of Marshall, MI (616-781-4241), as the predicate device for the ChillBuster® Model 8001 Portable Electric Blanket System.

Device Description

The ChillBuster® Model 8001 Portable Electric Blanket System is made up of six major components:

- Blanket. This main functional element of the System features a waterproof nylon outer layer, and an inner layer of soft polar fleece. Lying between the latter two layers and attached to the internal aspect of the polar fleece is a unique pattern of special thermal wire and, at one point in the wire array, a wire-adjacent thermistor. The Blanket is machine washable;
- Control Module. Four key subunits form this component: 1) one electronic circuit board (ECB) where all control and operating electronics reside; 2) one User Interface Panel, providing information, controls and cable connectors; 3) Interconnect Wiring; and 4) a Molded Chassis that forms the base for the other components, along with a recessed compartment for the system Battery;

- **Battery.** The Model 8001 employs a sealed lead acid, rechargeable Battery. The Control Module will accept two different Battery configurations, of 7 Amp-Hour and 4 Amp-Hour capacity, respectively. The purchaser specifies the desired Battery capacity at the time of purchase;
- **Cabling.** A single Blanket Interconnect Cable is standard, extending from the Control Module to a mating connector at one Blanket corner. One optional cable is also available, allowing connection of the Model 8001 System to a vehicle cigarette lighter socket, permitting the alternative of obtaining external System power for direct System operation and simultaneous System battery recharging;
- **AC Adapter.** All Model 8001 Systems include a standard AC-to-DC Adapter properly matched to the voltage, current and interconnect requirements of other System components; and
- **Carrying Bag.** ChillBuster® Model 8001 Systems include a custom Carrying Bag. The Carrying Bag conveys no impact on system safety.

Intended Use

The ChillBuster® Model 8001 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.

Non-Clinical Performance Data

A. Formal Studies Conducted Independent of ThermoGear™

The studies reported in this subsection were conducted by the product Safety group at Northwest EMC, Inc., an independent commercial firm accredited to test and certify equipment on behalf of numerous agencies worldwide, including TUV Rheinland. The 8001 system passed all tests.

Standards. The Model 8001 System has been tested to the following standards:

General Medical Safety: IEC 601-1:1998; Amd. 1: 1991; Amd. 2: 1995
UL 2601-1

EMC: IEC 601-1-2

Verification of 8001 Operation.

The Model 8001 was set up and operated according to the Operating Manual. In Verification Test #1, the Model 8001 was found to generate distributed, low-level active heat throughout the intended operating range of user intensity settings. In Verification Test #2, the Model 8001 demonstrated a progressive lengthening of functional blanket heat delivery sessions (a direct function of battery life) as the operator-set temperature setting was varied from highest to lowest setting. Northwest EMC deemed that the Model 8001 successfully met all product specifications under simulated in-use test conditions.

Comparison to Predicate Device.

The Model 8001 was set up and operated according to the Operating Manual under two configurations, using internal and external 12 VAC battery power, respectively. The predicate device was operated according to its Operating Manual, powered from 120 VAC. All tests were conducted at the highest available temperature settings. In Comparison Test #1, all three test runs demonstrated distributed, low-level active heat production, the predicate showing higher average heat output (note that its highest setting of 110F exceeds the comparable figure of 105F for the 8001), while both Model 8001 configurations demonstrated more even heat distribution than the predicate. In Comparison Test #2, the same basic setups were used to compare operation of both Model 8001 configurations and the predicate at different ambient temperatures. All three systems revealed distributed, low-level active heat production as before, although the predicate showed little extra heat production over either of the Model 8001s, while heat distribution uniformity in this test series was of similar character for all three systems.

B. Informal Studies Conducted by ThermoGear™

The following items represent informal tests or observations that corroborate the formal test results cited above:

Warming Performance. Complete 8001 systems were informally tested by a large number of independent subjects (estimated to exceed 50 individuals) in the course of late-term ThermoGear™ product development and design. Every subject reported 8001 system behavior to be the rapid rise of blanket temperature to a moderate, comfortable level, which thereafter remained essentially constant for the duration of sampling;

Adverse System Performance. No adverse conditions of the equipment or its performance were encountered in the informal 'Warming Performance' testing cited above;

Machine Washing Performance. The 8001 System was functionally tested after subjecting the system Blanket to ten consecutive cycles of machine washing (cold water; gentle agitation; home detergent; no bleach) and machine drying (low temperature; gentle cycle). No degradation of blanket temperature rise time or routine operating heat delivery was apparent to manual palpation over the full area of the blanket. There was also no compromise to the blanket, functionally or otherwise, apparent to visual inspection;

Conclusions Drawn from Non-Clinical Tests

In conclusion, across all formal tests conducted by Northwest EMC and the informal ThermoGear™ tests reported above, the 8001 system performed according to specification, compared favorably to the Predicate device, and no new issues of safety or effectiveness were found to arise in the 8001 System compared to the Predicate device.

Comparison of Technological Characteristics (8001 vs Predicate Device)

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

FEATURES	MODEL 8001 SYSTEM	LIFE-AIRE 1000 SYSTEM
Indications for Use	counteract hypothermia	counteract hypothermia
Function	low-level distributed heat to patient	low-level distributed heat to patient
Heat Delivery Mechanism	conduction	convection
Heat Source	thermal wire in blanket	heater in blanket input manifold
Electrical Requirements	12 VDC @ 3.2 Amp	120 VAC, 60 HZ, @ 7 Amp
Heating Element Power	about 40 W	about 700 W
Max Heat Presented to Patient	105F	110F
User Heat Output Control	uncalibr'd continuous, ~20W-40W	discrete steps, 80F/90F/100F/110F
Thermal Temperature Cutoff	105F @ blanket wire surface	120F @ blanket inlet manifold
Alarms	none	1 audio; 1 visual
Circuit Protection	fused positive battery lead	power supply circuit breaker
Internal Diagnostics	none	auto or manual self-test sequence
Safety Agency Approvals	TUV Rheinland	UL544; CSA
EMC Compatibility Testing	IEC 601-1-2	unavailable to ThermoGear™
Cross-Contamination Protection	sterile, single-use blanket cover	sterile, single-use blanket
Blanket Material(s)	oxford nylon & nylon acrylic	unavailable to ThermoGear™
Control Unit Construction	flame-retardant polycarbonate	16 ga. steel; baked enamel finish
Blanket Cleaning	machine washable & dryable	disposed after single use
System Weight	8 lbs	35 lbs



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR -1 2000

Dr. R. Wayne Fields
Senior VP
ThermoGear™ Inc.
180015 Lower Boones Ferry Road
Tigard, OR 97224

Re: K991684/S2
Chillbuster Portable Electric Blanket System, Model 8001
Regulatory Class: II (two)
Product Code: DWJ
Dated: February 18, 2000
Received: February 22, 2000

Dear Dr. Fields:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

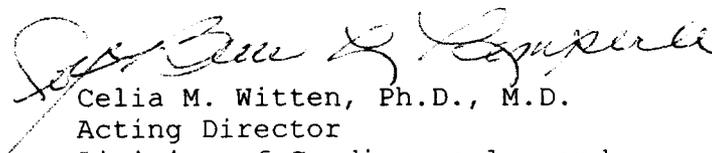
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Dr. R. Wayne Fields

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

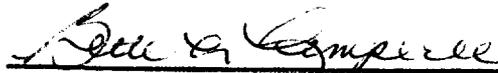
Enclosure

510(k) NUMBER (IF KNOWN): K991684

DEVICE NAME: Model 8001 Portable Electric Blanket System

INDICATIONS FOR USE:

The ChillBuster® Model 8001 Portable Electric Blanket System 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.



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K991684

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-9)