K051278

RG Medical Diagnostics

JUN 29 2006

510(k) Premarket Notification Summary

Geratherm® SOS-Vacutherm

Common Name – Warming Blanket
Classification name - Thermal Regulating System (870.5900) AND
Stretcher, Hand Carried (21 CFR, 880.6900)
Predicate Device - ChillBuster™ Portable Electric Blanket (Thermogear, Inc. K991684)

The following material
presents the 510 (k) Summary
for the Geratherm® SOS-Vacutherm

21130 Bridge Street • Southfield, MI 48034
Phone: 888-596-9498 • Fax: 248-750-0187 • Website: www.rgmd.com

Premarket (510K) Summary

Submitter Information

RG Enterprises, Inc.
(dba) RG Medical Diagnostics
21130 Bridge Street
Southfield, MI 48034
888-596-9498
Date Prepared: 04/15/05

Device Name:

Proprietary name: Geratherm SOS-Vacutherm (Thermamed "Smartcare")
Common name: Hypothermic Therapy System
CDRH Product Regulation: Thermal Regulation System (21 CFR, 870.5900)

AND,

Stretcher, Hand Carried (21 CFR, 880.6900) (510(k) exempt)

Establishment Registration Number: 1835242

Classification: Combination Product, Class II (DWJ) AND Class I (FPP)

Predicate Device:

RG Medical Diagnostics, 21130 Bridge Street, Southfield, Michigan, 48034 has designated The **Chillbuster Portable Electric Blanket System, Model 8001,** (K991684) manufactured by Thermogear, Inc. 18005 Lower Boones Ferry Rd., Togart, OR 977224 as the Predicate Device for the Geratherm SOS-Vacutherm System, manufactured by Geratherm AG, Fahrenheitstrasse 1, D-98716 Geschwenda/Germany.

Statement of Substantial Equivalence:

Geratherm SOS-Vacutherm Optimal is substantially equivalent to:

1. ChillBuster™ Portable Electric Blanket (Thermogear, Inc. K991684)

Description of Device:

The Geratherm SOS-Vacutherm System is a combination product made of two primary components:

1. An electrically warmed panel. - Class II

2. A integrated vacuum mattress / stretcher - Class I (exempt from 510(k) premarket notification).

Vacutherm description:

1. Warming Panel: The main functional warming panel element is a 54 inches (137.0 cm) by 31.5 inches (80.0 cm). The active warming panel is constructed of electrically resistive carbon fiber woven cloth enclosed between two layers of Dacron® polyester hollow fiber fleece panels. The carbon fiber cloth is stitched to a lower fleece panel. The polyester fleece layers are permanently enclosed in a waterproof polyurethane / polyester cloth laminate cover. The active warming panel has a permanently affixed power cable that is attached to the power control module via color coded quick connect power connections. The active panel is attached to the vacuum mattress with quick attach / disconnects.

2: Insulated Heat Reflective Panel: A reflective panel overlays the active panel from the opposite side of the patient. The passive insulation panel is attached to the vacuum mattress on the opposite side of the active panel with quick attach /disconnects.

3. Control Module: The control module is a molded high impact plastic housing that contains the electronic circuitry. The module regulates the warming panel temperature through a feedback circuit employing two thermistor temperature sensing systems located in the interior of the SOS-Vacutherm warming panel. Operator control is achieved through the use of four buttons located on the face of the module: an on button, off button, a 37° C (98.6°F) select button, and a 42° C (107.6°F) select button. The control module displays both warming panel temperature level and battery power status. Normal functions are monitored both through visual displays and audible signal. The control module power sources are the following; the auxiliary battery, an automotive type 12 Volt power supply outlet, or an aircraft power supply outlet, The control module automatically adjusts output current to either 12 volt DC automotive or 24-28 volt DC aircraft power sources. The control module body may be attached to the warming panel using a form-fitting pocket that is permanently attached to the insulated heat reflective panel.

4. Battery: The Geratherm SOS-Vacutherm system uses a sealed lead-acid gel rechargeable battery of 10-ampere hour capacity.

5. Cabling: The Geratherm SOS-Vacutherm System has a power cable permanently attached to the upper corner. The cable attaches from the warming panel directly to the Control Module. The cable supplying power to the power module has a color-coded quick connect at one end and an auxiliary battery /automotive/aircraft DC power outlet at the other.

6. AC to DC Charger: The Geratherm SOS-Vacutherm System employs a 12 volt, DC, 2-ampere hour output battery charger to charge the battery or maintain full battery status. The charger may be used with either 120 or 240 Volt, 50 or 60 Hertz, AC input electric current.

Intended Use

The Geratherm SOS-Vacutherm system is designed to prevent or reduce the effects of hypothermia and hypothermia related symptoms. It may be used in the transport of trauma victims or critical care patients to a hospital by ambulance, helicopter, or fixed wing aircraft. Using the Geratherm® SOS Vacutherm System lowers susceptibility to shock caused by the cold. In addition, patients experience a subjective reduced perception of pain.

Non-Clinical Performance Data

The studies reported in this subsection were conducted by CE-LAB GmbH, iMG gGmbH, TREO Electrooptik GmbH, and TÜV GmbH

Standards: The Geratherm SOS-Vacutherm has been tested to the following standards:

General Medical Safety:
EMC Specification EN 60601-1-2:2001.
NATO Standard DCS01, DCE01.
Generic Specification of SPAME (Special Purpose Aeromedical Equipment) Issue 3, page 16, No. 62 (vibration).
IEC 60601-1:1990 + A1:1993 + A2:1995
IEC 60601-2-35:1996
EN 60601-2-35:1996
Œ 0118
ISO 13485:2003
UL AWM Style 1007 & 1589
UL VW-1 FT

Clinical Performance Data

A formal clinical evaluation was performed at the Mayo Clinic comparing passive warming and active warming using Geratherm resistive carbon fiber electrical warming technology.

Alexander Kober, MD; Thomas Scheck, BS; Béla Fülesdi, MD; Frank Lieba, BS; Wolfgang Vlach, BS; Alexander Friedman, MD; & Daniel I. Sessler, MD , "Effectiveness of Resistive Heating Compared With Passive Warming in Treating Hypothermia Associated With Minor Trauma: A Randomized Trial," *Mayo Clinic Proc.* 2001;76:369-375

Results: Patients who were transported using Geratherm electric / carbon fiber active warming systems experienced significantly lesser degrees of hypothermia than those who were transported using passive warming techniques.

Verification of Operation Under Non-Laboratory Conditions

The Geratherm SOS-Vacutherm System was tested according to the Operating Manual.and was found to prevent or reduce hypothermia by the following organizations:

CE 0118

SAMU 38 – Helicopter Mountain Rescue
Grenoble, France

ADAC Helicopter Helicopter Rescueservice
Munich, Germany

Royal Dutch Army, Helicopter Catastrophe Rescueteam
Netherlands

REGA - Mountain rescue service
REGA – Centre Zürich Airport
Zürich, Switzerland

Conclusions Drawn from Clinical and Non-Clinical Testing

The Gerathrerm SOS-Vacutherm System performed according to specification and compared favorably to the Predicate Device. No new issues of safety or effectiveness were found to arise in the Geratherm Vacutherm System when compared to the Predicate Device

Comparison of Technological Characteristics (SOS - Vacutherm vs Predicate device)

Features	Geratherm® SOS -Vacutherm	ChillBuster™ Model 8001
Indications for Use	Preventing / counteracting hypothermia	Preventing / counteracting hypothermia
Function	Low-level distributed heat to patient	Low-level distributed heat to patient
Heat Delivery Mechanism	Conduction	Conduction
Heat Source	Resistive carbon fiber cloth in panel	Thermal wire in blanket
Electrical Requirements	12 VDC & 24-28 VDC @ 7 Amp	12 VDC @ 3.2 Amp
Heating Element Power	120 W (max)	40 W (approx.)
Heat Presented to Patient	37° C (98.6° F) or, 42° C (107.6° F)	105° F
User Heat Output Control	Regulated 37° C or, Regulated 42° C	Un-calibrated continuous 20W-40W
Thermal Temperature Cutoff	37° C (98.6° F) or, 42° C (107.6° F)	105° F
Alarms	Audible and Visual	none
Circuit Protection	Multiple fault sensors, circuit breaker and fused controller	Fused positive battery lead
Internal Diagnostics	Continuous automatic self testing	none
Safety Agency Approvals	TUV Munich	TUV Rheinland
EMC Compatibility Testing	IEC 601-1-2	IEC 601-1-2
Cross-Contamination Protection	Disposable single use liner	Disposable single use liner
Cytotoxicity	L 929-Proliferation; EN 30993-5,-12; OSI 10993-5,- 12; LM SOP 4-06-01	
Controller Diagnostic Display	Panel temperature, battery power level, fault detection, fault identification	
Blanket Material	Polyurethane and Dacron® polyester cloth laminate with Dacron® hollow filament fleece interior	Oxford nylon and nylon acrylic
Control Unit Construction	Impact resistant polycarbonate	Flame retardant polycarbonate
Cleaning	Hand wash all segments	Machine wash and dry
System Weight	19 lbs (8.7 kg)	8 lbs
Disinfection	Suitable for spray or sponge applied water based disinfectants	No information

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2006

R.G. Enterprises, Inc.
c/o Mr. Ronald G. Letoutneau
President
21130 Bridge Street
Southfield, MI 48034

Re: K051278
Geratherm SOS-Vacutherm
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (Two)
Product Code: DWJ
Dated: June 21, 2006
Received: June 23, 2006

Dear Mr. Letoutneau:

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.

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachner

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): K051278

Device Name: Geratherm SOS-Vacutherm

Indications For Use:

The Geratherm SOS-Vacutherm is a temperature-controlled electric whole body warming system intended for use in preventing or treating the effects of incidental hypothermia in adults while at the rescue scene or during transport by air or ground to a medical facility

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachuska

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051278