K062794

DEC - 7 2006

SECTION III

PREMARKET NOTIFICATION (510K) SUMMARY

(Per 21 CFR 807.92)

Submitted by:

American Healthcare Products, Inc.
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Contact Person:

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Date Prepared: January 2005

Device Name:

Trade Name:	PRN ThermalCare Patient Warming System: Model 3000
Common Name:	Hyperthermia System/Thermal Regulating System
Classification Name:	Thermal Regulating System
Product Code & Reg. No.	DWJ, 21CFR 870.5900

Substantially Equivalent:

The PRN ThermalCare Patient Warming System Model 3000 is substantially equivalent to the following devices:

Klimamed Thermal Mat & Controller 95 &55	**The Bair Hugger® Model 750 Temperature Management System**	**Kimberly-Clark Patient Warming System Model 100 Control unit and Energy Transfer Pads**
KO11859	**KO01149**	**K033021**

Description of the Device: The PRN ThermalCare patient warming system, Model 3000 system includes a pressure reducing, thermal regulated mattress, which is placed beneath the patient, and a separate control unit. The mattress contains a carbon fiber heating element for which the control unit, when connected, supplies low voltage DC current, providing low level conductive heat (preset between 36◦C and 40◦C) to the patient.

Section III: Premarket Summary- continued

Indication for Use: By physicians in clinics and hospitals, the PRN ThermalCare Patient Warming System is intended to aid in maintaining the surgical patient's body temperature, before, during and after surgery. The heated pressure relieving surgical mattress is available in various lengths and is intended for use on operating tables, surgical and diagnostic surfaces in hospitals or surgical centers to prevent and treat hypothermia and to reduce the occurrence of pressure sores.

Patient Population: Pediatric and Adult.

Environment of Use: Hospitals and surgical centers operating rooms

Contraindications: Do not use during surgical procedures that require patient hypothermia during operation. Consult with patient physician or anesthesiologist to determine if anti-hypothermia treatment is desired

Comparison to Predicated Devices: See attached comparison: Table 1
The differences between PRN ThermalCare 3000 and the predicated devices are minimal: These predicated devices are all external, thermal regulating systems that consist of a device that is placed in contact with the patient and a microprocessor -based control unit that provides physician determined temperature control.

Testing Safety and Effectiveness: Testing of the safety of PRN ThermalCare Patient Warming System Model 3000 were reviewed and found in accordance with the requirements in UL 2601-1, CSA C22.2 No. 60601-1 and IEC 60601-2-35 . The operational integrity testing conducted, demonstrated the device met the performance/effectiveness parameters.

Conclusion: Based upon the testing and comparison we believe the PRN ThermalCare Model 3000 to be substantially equivalent to predicated devices and that there is no new safety or effectiveness issues.

Section III
Table 1: Comparison to Predicated Devices

	PRN ThermalCare 3000 Patient Warming System	**Klimamed Thermal Mat & Controller 95 &55**	**The Bair Hugger® Model 750 Temperature Management System**	**Kimberly-Clark Patient Warming System Model 100 Control unit and Energy Transfer Pads**
519(K) No.		KO 11859	K001149	K033021
Intended Use	Patient warming	Identical	Identical	Identical
Clinical areas for Device Use	Hospital environment & Surgical Centers	Identical	Identical	Identical
Patient Population	Pediatric and adult	Identical	Identical	Identical
Device Positioning	Control unit is placed on hard surface, shelf, OR pedestal, IV Pole Pad is in external contact with the Patient	Identical	Identical	Identical
Technology Used	Conductive Heating Carbon Fiber Heating	Similar: Conductive Heating Carbon Fiber	Different: Convective Heating Forced air	Similar: Conductive Heating water
Over temperature detection	2 completely independent systems	Similar: Independent redundant safety system	Similar: Independent electronic circuit. Thermal cutoff shuts heater off at preset hi temp	Similar: Temperature probe connected to control module. Temp is controlled by altering temp of circulating water
Standards Meet	UL 2601-1 IEC 60601-2-35 CSA 22.2 60601-1	IEC 60601 & 60602	UL 2601 & EN 60601	IEC 601 EN60601 ISO 10993-1
Alarms	Visual/Audible	identical	identical	identical
Control circuitry	Microprocessor-based	identical	identical	identical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

American Healthcare Products, Inc.
c/o Mr. Kent D. Ellis
Quality and Compliance
3220 South Hanford Street
Seattle, WA 98144

DEC - 7 2006

Re: K062794
PRN ThermalCare Patient Warming System Model 3000
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: November 17, 2006
Received: November 20, 2006

Dear: Mr. Ellis:

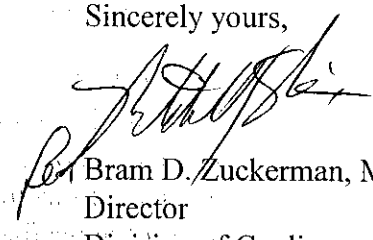
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (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

SECTION II

STATEMENT: INDICATION FOR USE

510 (k) Number K062794

Device Name: PRN ThermalCare Patient Warming System
Model: PRN ThermalCare 3000

Indications for Use: The PRN ThermalCare patient warming system is intended to aid in the maintenance of patient normal thermia (maintaining normal body temperature of 36C) before, during and after the perioperative experience (surgery) for Pediatric and Adult patients. Conductive warming temperatures for the patient are selected by physicians (anesthesiologist or nurse anesthetist) or according to facility hypothermia protocol. Pressure reduction is achieved within the pad design. The pressure reducing properties are effective for Patients up to 500 lbs./225k

Prescription Use ___X___ Over the Counter Use _____
(Part 21 CFR 801 Subpart D) and/or (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062794