VITA HEAT medical

6. 510(k) Summary per 807.92(a)(1)

Date Prepared: July 31, 2013

Submitter's Information

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OCT 04 2013

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Proposed Device

Common Name:	VITAHEAT™ Patient Warming System
Classification name:	Thermal Regulating System
Class:	Class II /21CFR 870.5900
Product Code:	*DWJ*
Regulatory Class:	Class II (Two)

Indications for Use

The VITAHEAT™ Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The VITAHEAT™ Patient Warming System should be used in circumstances in which patients may not maintain a state of normothermia.

The System is intended primarily for use in hospitals and surgical centers including without limitation operating, recovery and emergency rooms and on medical/surgical floors.

Description of Device

The VITAHEAT™ Patient Warming System consists of a Controller, a reusable Warming Mattress, single use disposable covers and accessories. The Controller is powered by a rechargeable 18V lithium ion battery and a separate charging unit is provided with the device. Each System also includes a second rechargeable 18V lithium ion battery to allow for uninterrupted operation. Typical battery life is 3-5 hours maximum on a fully charged battery depending on the usage. Other accessories provided with the device include a non-heating Thigh Pad that may be used by the patient for thigh support while lying on the mattress and an extension cord to connect the Controller to the Warming Mattress. The specific mechanism of action/heating is detailed further in Section 12.3.

To operate the VITAHEAT™ Patient Warming System, the Controller is connected to the reusable Warming Mattress using the extension cord provided with the device. The Controller may be placed on hospital bed rail, stretcher rail or on patient bed. The reusable Warming Mattress is then placed into a pocket on a single use disposable sheet cover also provided with the device. The patient then lies on top of the covered Warming Mattress for safe warmth. After the patient is in position on the covered Warming Mattress, it is recommended that the VITAHEAT™ Thigh Pad be placed under the patient's thighs to provide thigh support.

The VITAHEAT™ Patient Warming System is designed to be controlled by either the patient or the clinician. The output temperature range of the device is $35^{0}C - 38.5^{0}C \pm 1.5^{0}C$; temperatures are adjusted to depending on the power setting selected by the user. From the time the device is turned ON, it takes 8-10 minutes for the Warming Mattress to reach the maximum temperature of $38.5^{0}C \pm 1.5^{0}C$ when the highest power setting is selected. When the 'LOWER' button is pressed, the desired temperature setpoint is lowered and correspondingly when the HIGHER button is pressed, the setpoint is raised gradually. A different set of LED lights on the Controller indicate the battery life. If the temperature of the Warming Mattress exceeds a maximum safety limit of $41^{0}C$, an automatic system cutoff initiates and the energy to the Warming Mattress is discontinued and the unit becomes inoperable.

Below is a picture of the complete VITAHEAT™ Patient Warming System:

The VITAHEAT™ device contains a controllable thermal warming component comprised of a series of connected lines printed with conductive ink on a substrate. The components of this device are given in the table below:

Table 6A: Product Components

S. No.	Component	Quantity Supplied	Use
1	Controller	1	Device used to accurately control the temperature of the Warming Mattress per user selected levels.
2	Warming Mattress	1	Using the energy supplied by the Controller to provide warmth to the patient
3	Non-heating Thigh pad	1	To provide thigh support to the patient as he/she lies down on the Warming Mattress
4	18V rechargeable lithium ion battery	2	Batteries are used to power the Controller that supplies electrical energy to the Warming Mattress. Additional battery is provided as a backup once the original battery is drained after 3-5 hours of continuous use.
5	Battery Charging Unit	1	To charge the 2 rechargeable lithium ion batteries provided with the device

6	Single use disposable covers	24	To cover the Warming Mattress when it is used to supply warmth to a patient as a layer between the Mattress and the patient
7	Detachable extension cord	1	To supply the energy from the Controller to the Warming Mattress
8	Battery Charger Power Supply	1	To connect the Battery Charger to A/C mains
9	Instructions for Use booklet	1	To provide instructions for use, safety features, system precautions and warnings

Table 6B below gives the details on the device component properties

Table 6B: Component Properties

S. No.	Component	Patient Contact (Yes/No)	Provided Sterile or Non-Sterile	Single Use or Reusable
1	Controller	No	Non-Sterile	Reusable
2	Warming Mattress	No*	Non-Sterile	Reusable
3	Non-heating Thigh pad	No	Non-Sterile	Reusable
4	18V rechargeable lithium ion battery	No	Non-Sterile	Reusable
5	Battery Charging Unit	No	Non-Sterile	Reusable
6	Single use disposable covers	Yes	Non-Sterile	Single Use
7	Detachable extension cord	No	Non-Sterile	Reusable
8	Battery Charger Power Supply	No	Non-Sterile	Reusable
9	Instructions for Use booklet	No	Non-Sterile	Reusable

**Since the disposable cover provides a layer between the patient and the Warming Mattress, the Warming Mattress does not directly come into contact with the patient; however blood, soils, etc. could leak through the cover and touch the mattress, thus, a cleaning method validation is discussed in Section 15 of this 510(k).*

Predicate Device

Hot Dog Patient Warming Mattress System by Augustine Biomedical & Design LLC, (**K092807**).

Summary of Technical Characteristics

The VITAHEAT™ Patient Warming System was compared to the predicate device in areas of components, packaging and compatibility with material, design, and size range. The VitaHEAT device is considered to be substantially equivalent to the predicate device Hot Dog Patient Warming Mattress System by Augustine Biomedical & Design LLC, (**K092807**).

Per 21 CFR Part 807.92(a)(5), the following shows where the VitaHEAT device is similar and different in terms of technological characteristics. A comparison between the new and predicate device shows that the technological characteristics and indications for use are equivalent.

Summary of Non-Clinical Testing/Statement of Equivalence

The VITAHEAT™ Patient Warming System was designed, developed, tested and validated according to written procedures. Multiple tests concerning product functionality, biocompatibility, packaging and sterilization have been performed to ensure that the VITAHEAT™ device is as safe and as effective as the predicate device. Specific testing included the following:

- **Cleaning:** A cleaning method validation of patient contacting components supplied
- **Packaging:** Drop testing, simulated shipping and overall packaging validation
- **Biocompatibility:** Cytotoxicity, Irritation and Sensitization testing
- **Software:** A complete testing of the software used in the device
- **Electromagnetic Compatibility and Electrical Safety:** Keeping in mind that the VITAHEAT™ device is battery operated, electrical safety testing per relevant standards was conducted

- **Temperature Performance Testing:** Testing was conducted to show that the device is able to achieve the temperature range that is provided in the labeling and is able to maintain a heating set point once steady state is reached
- **High Temperature Cutoff Testing:** Testing to show that the VITAHEAT™ device shuts off at an acceptable predetermined cutoff temperature of 41°C
- **Pressure & Burns Safety Testing:** Testing was conducted to show that even when pressure is applied to any portion of the device, a surrogate for pressure points of the human body such as elbows, head, buttocks etc, the temperature on the surface of the device does not exceed the threshold temperature that could cause thermal injury to patients.
- **General** functional, mechanical, dimensional and other performance testing against pre-determined specifications

The system is designed to meet the following performance standards:

- **IEC 60601-1: 1998 + A1:1991 + A2:1995** Medical Electrical Equipment - Part **1:** General Requirements For Basic Safety And Essential Performance, edition 2.
- **IEC 60601-2-35** Particular requirements for the safety of Disposable Covers, pad and mattresses intended for heating in medical use, edition **1.**

Conclusion

The VITAHEAT™ device has the same indications for use, similar scientific fundamental technology, materials and packaging as the predicate device. The VITAHEAT™ device has very similar technological characteristics to the predicate and both have the same general shape, size and identical principles of use. Both devices contain a Patient Warming Mattress and a Temperature Controller that provides energy to the Warming Mattress and controls the heat it provides to the patient. Both devices are provided non-sterile and contain no components that are meant to be sterilized. Both devices have identical patient positioning and nearly identical device positioning requirements. Both have the same set of single use and re-usable components. Both devices have nearly identical patient contacting components and use a similar patient barrier, each of which has been tested for biocompatibility safety as per ISO 10993-1. Both devices have identical environmental conditions for storage, transportation and use.

Although there are certain differences between the VITAHEAT™ device and the predicate, these differences do not raise any new concerns in terms of safety and efficacy. For example, in terms of power source requirements, the predicate device requires an A/C mains power source whereas

the VITAHEAT™ device is battery operated, making the VITAHEAT™ device safer to operate in this aspect.

The data and information provided in this submission supports a substantial equivalence determination and, therefore, 510(k) premarket notification clearance of the VITAHEAT™ system.. *The minor technological differences such as shape, size, and compatibility have been evaluated through multiple verification and validation activities as well as critical analyses. Results of these evaluations demonstrate that these differences do not affect the ability of the VITAHEAT™ to achieve the indications for use. The VITAHEAT™ system does not raise any new questions regarding safety or effectiveness of the device, compared to the predicate Hot Dog device and is therefore substantially equivalent.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 4, 2013

VitaHEAT Medical, LLC
c/o Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K132454
Trade/Device Name: VitaHEAT Patient Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: August 9, 2013
Received: August 12. 2013

Dear Mr. Job:

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 contact 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. 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use Statement

510(k) Number (if known): K132454 (*To be assigned*)

Device Name: VITAHEAT™ Patient Warming System

Indications for Use: The VITAHEAT™ Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The VITAHEAT™ Patient Warming System should be used in circumstances in which patients may not maintain a state of normothermia.

The System is intended primarily for use in hospitals and surgical centers including without limitation operating, recovery and emergency rooms and on medical/surgical floors.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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