K092807

Section 5
Premarket 510k Summary

DEC 10 2009

Submitter Information:
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6581 City West Parkway
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952.465.3500

Contact:
James D. Ecklein, Director RA/QA

Date Prepared:
December 10, 2009

Trade Name
Hot Dog Patient Warming Mattress System
Model Numbers: WCUB, M101, M102, M103

Product Code
DWJ (21 CFR Part 870.5900)

Common Name
Thermal Regulating System

Predicate Device
Inditherm Patient Warming System - K051419
Hot Dog Patient Warming System - K052392
Bair Hugger Patient Warming System Model 505 - K960167
Bair Hugger Patient Warming System Model 750 - K001149

Device Description
The Hot Dog Patient Warming Mattress System consists of a temperature control unit that monitors and controls the temperature of a patient warming mattress. The mattress is composed of a conductive polymer coated fabric heater encased in a polymer shell. The mattress also contains a pressure relieving foam pad.

Intended Use
The Hot Dog Patient Warming Mattress System is intended to prevent or treat hypothermia and to provide warmth to patients. The Hot Dog Patient Warming Mattress should be used in circumstances in which patients may not maintain a state of normothermia. The mattress includes a pressure relieving pad. 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.

Technological Characteristics
A comparison between the new and predicate devices shows that the technological characteristics and indications for use are equivalent. The products have similar designs, materials, components and dimensions.

Non Clinical Data
Bench testing was performed to demonstrate that the proposed warming mattress system is substantially equivalent to the predicate devices. Temperature characteristics, pressure relief characteristics and safety systems were compared and found to be

comparable. The mattress system is designed to meet the following performance standards:

IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance, edition:

IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, edition.

IEC 60601-1-4:2000, Medical electrical equipment - Part 1: General requirements for safety - 4 - Collateral standard: Programmable electrical medical systems, edition 1.1.

IEC 60601-2-35 Particular requirements for the safety of blankets, pad and mattresses intended for heating in medical use

Clinical Data

Not required

Conclusion

The Hot Dog Patient Warming Mattress System was found to be equivalent to the predicate devices in technological characteristics and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Augustine Biomedical & Design LLC
c/o Mr. James D. Ecklein
Director RA/QA
6581 City West Parkway
Eden Prairie, MN 55344

DEC 10 2009

Re: K092807
Hot Dog Patient Warming Mattress System, Model Numbers: WCUB, M101, M102, M103
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: August 31, 2009
Received: September 11, 2009

Dear Mr. Ecklein:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K092807

Device Name: Hot Dog Patient Warming Mattress System

Indications For Use:

The Hot Dog Patient Warming Mattress System is intended to prevent or treat hypothermia and to provide warmth to patients. The Hot Dog Patient Warming Mattress should be used in circumstances in which patients may not maintain a state of normothermia. The mattress includes a pressure relieving pad.

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)

Donna R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092807