K112488

Section 5
510k Summary

NOV 23 2011

Submitter Information:	Augustine Biomedical & Design, LLC 6581 City West Parkway Eden Prairie, MN 55344 952.465.3500
Contact:	Wendy J. Nelson, Director RA/QA
Date Prepared:	8/10/2011
Trade Name	HotDog Patient Warming System Model Numbers: WC0X, WC5X, BXXX, UXXX
Product Code	DWJ (21 CFR Part 870.5900),
Common Name	Thermal Regulating System
Predicate Device	HotDog Patient Warming System K052392
Device Description	The HotDog Patient Warming System consists of a temperature control unit that monitors and controls the temperature of a patient warming blanket or mattress. The blankets and mattresses are 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 System is intended to prevent or treat hypothermia and to provide warmth to patients. The Hot Dog Patient Warming System should be used in circumstances in which patients may not maintain a state of normothermia. The patient warming system can be used with adult and pediatric patients. 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 device shows that the technological characteristics and indications for use are equivalent. The products have similar designs, materials, components and dimensions.

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Non Clinical Data

Bench testing was performed to demonstrate that the proposed warming system is substantially equivalent to the predicate devices. Temperature characteristics and safety systems were compared and found to be comparable. The 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 2.

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

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, edition 1.

Clinical Data

Not required

Conclusion

The HotDog Patient Warming System was found to be equivalent to the predicate device in technological characteristics and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Augustine Biomedical & Design LLC.
c/o Ms. Wendy Nelson
Director of Regulatory Affairs
6851 City West Parkway
Eden Prairie, MN 55344

NOV 23 2011

Re: K112488
Hot Dog Patient Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: August 22, 2011
Received: August 29, 2011

Dear Ms. Nelson:

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,

M. J. Hillebrenner

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

Enclosure

Section 4
Indications For Use Statement

Indications for Use

510(k) Number (if known): K112488

Device Name: HotDog Patient Warming System

Indications For Use:

The HotDog Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The HotDog Patient Warming System should be used in circumstances in which patients may not maintain a state of normothermia. The patient warming system can be used with adult and pediatric patients.

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)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112488