Geratherm®
Medical Diagnostic Systems

K093244

510(k) Summary as required by section 807.92(c) 10/19/2010

Submission Applicant:
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OCT 19 2010

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Trade Name: Geratherm UniqueTemp°

Common Name: Warming systems / blankets

Classification Name: Thermal regulating systems (21 CFR 870.5900, Product code DWJ)

Substantial Equivalence Warming System:
510(k)-Number: K052392 – Hot Dog Patient Warming System
Firm: AUGUSTINE BIOMEDICAL & DESIGN, LLC

Description of the Device:
Geratherm UniqueTemp° has been developed for the prevention of hypothermia. The Geratherm warming blankets can be used for covering the patient in various ways without restricting the

surgical area and provide active warming to the patient. All the blankets can be freely combined. The flexibility of the blankets makes it possible to warm the patient, even if complicated positioning on the operating table is required. After being placed over the patient, Geratherm UniqueTemp° can itself be covered with surgical drapes.

Geratherm UniqueTemp° is suitable for use with adult patients of all sizes. The blankets should not be used for children.

Geratherm UniqueTemp° is intended to be used during lengthy operations as well as by hypothermic patients. The device is not life-supporting. Geratherm UniqueTemp° should be operated only by qualified medical professionals.

The Geratherm UniqueTemp° consists of the following components:

- Control unit
- Holding claw
- Mains cable
- Arm/shoulder blanket
- Reusable cover for arm/shoulder blanket
- Torso blanket
- Reusable cover for torso blanket
- Leg blankets
- Reusable cover for leg blankets
- Connecting cable
- Body temperature sensor

The Controller is made of anodized aluminum (colorless or black); furthermore, the control unit has a glass screen. All blankets and covers have a PU coated material. The connecting cable is made of silicone.

Indications for Use:
Geratherm UniqueTemp° is a thermal regulating system for adult patients in order to prevent hypothermia in the operating theater. It is suitable for pre-, intra-, and post-operative use. The device is not life-supporting. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Comparison with Predicate Device:
The Geratherm UniqueTemp° is identical to the predicate device in intended use, indications for use, where it is used, method of operation, safety characteristics, standards which are met (whereas the Geratherm UniqueTemp° complies with a wider range of standards than the predicate device), used material and sterilization instructions. However, unlike the predicate device, the UniqueTemp° has reusable covers which are steam permeable and washable up to 95°C. Therefore, the new device can be cleaned much easier.

The main technical characteristics are similar between the new and predicate device, but the UniqueTemp° has some new components. For instance, the new device has a color (TFT 3.5") temperature display with a touch screen and individual blanket control. Furthermore, the UniqueTemp° is equipped with a temperature pre-selection from 37°C up to 42°C in increments of 0.1°C (the predicate device has 3 possible preset temperatures of 38°C, 40°C and 43°C).

The UniqueTemp° is different from the predicate device in terms of the target population. The new device should be used for adult patients of all sizes, but not for children, whereas the Hot Dog Patient Warming System is intended for all patients.

Both devices are similar regarding the performance characteristics and reach a similar maximum temperature of 42°C and 43°C respectively. The only difference is the output power of the control unit, which does not raise questions regarding safety and effectiveness. Thus, the UniqueTemp° Patient Warming System is substantially equivalent to the predicate device.

Non-Clinical Performance Data:
Geratherm UniqueTemp° meets the requirements of Council Directive 93/42 EEC of 14.06.93 on Medical Devices and of the standard IEC 60601-1 (Medical electrical equipment, Part 1: General requirements for safety), IEC 60601-1-2 (Medical electrical equipment Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and Tests), and IEC 80601-2-35 (EMC, Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use). An EN ISO 13485 certified quality management system ensures that these requirements are met and entitles the manufacturer to use the CE 0118 label. Geratherm certifies compliance with relevant ISO/IEC/EN and other device-related standards.

Summary:

The substantial equivalence of the Geratherm UniqueTemp° and the referenced and approved earlier warming system, Hot Dog Patient Warming System (K052392), is based upon substantially similar methods for warming patients in the operating theater.

The presented data which was conducted using the Geratherm UniqueTemp°, in comparison to the predicate device, shows that the product is safe and effective for its intended use. The product components which are covered by this 510(k) premarket notification have been successfully tested for biocompatibility, electromagnetic compatibility, functionality and safety according to international standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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78532 Tuttlingen
Germany

OCT 19 2010

Re: K093244
Trade Name: Geratherm UniqueTemp° warming blankets
Dated: September 15, 2010
Received: October 7, 2010

Dear Ms. Pecsi:

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 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

Indication for Use

510(k) Number (if known): K093244

Device Name:
Geratherm UniqueTemp° Patient Warming System

OCT 19 2010

Indications for Use:

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K093244