SEP 20 2010

K093694

Geratherm®
Medical Diagnostic Systems

510(k) Summary as required by section 807.92(c)

9/17/2010

Submission Applicant:
Geratherm Medical AG
Thomas Robst
Fahrenheitstraße 1
98716 Geschwenda / Germany
Establishment Registration Number: 3003591690

Phone: +49 36205 98-0
Fax: +49 36205 98-116
E-mail: t.robst@geratherm.com

Application Correspondent/Contact:
RG Medical Diagnostics
Ron LeTourneau
28351 Beck Rd., Suite G5
Wixom, MI 48393 / USA

Phone: 888-596-9498
Fax: 248-504-6733
E-mail: rglt@rgmd.com

Trade Name: Geratherm UniqueResc+

Common Name: Warming systems / blankets

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

Substantial Equivalence Warming System:
510(k)-Number: K051097, GERATHERM SOS-RESCUE BLANKET,
RG ENT., INC., 28351 Beck Rd., Wixom, MI 48393

Description of the Device:

Geratherm UniqueResc+ has been developed for the prevention and treatment of hypothermia. The warming blankets are light-weight, comfortable and easily transportable.

The use of several blankets per patient is possible. The flexibility of the blankets makes it possible to warm the patient even during complicated rescue operating conditions.

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

Geratherm UniqueResc+ should be operated only by qualified medical professionals.

The benefits of Geratherm UniqueResc+ are:

- Active warming applied to the patient from superior side.
- State-of-the-art conductive material provides exceptionally uniform heating.
- Microprocessor-controlled
- Functions noiselessly
- Simple and easy to use
- Highly durable and easy to clean
- The optional Geratherm AC~DC Power Supply Adapter (see section 12.3 of the instruction manual for detailed description) functions with all alternating current mains power sources (100~240VAC, 50~60 Hz). Other optional power sources include 15VDC 2590 Li-Ion Battery and 12VDC-28VDC Onboard Power.

Indications for Use:
Geratherm UniqueResc+ is a thermal regulating system for adult patients in order to prevent hypothermia in preclinical settings or treatments on-site. It is intended for use while at the rescue scene, during patient transport by air or ground to a medical facility or e.g. during disaster operation in first aid tents. The device should be used by appropriately trained healthcare professionals.

Comparison with Predicate Device:
The Geratherm UniqueResc+ is identical in intended use, indications for use, target population, where it is used, method of operation, safety characteristics (both devices met mainly the similar standards), biocompatibility, used material (whereby UniqueResc+ has improved material characteristics), sterilization instructions and several technical characteristics. However, the main difference between the new and old device is that UniqueResc+ is not a full body blanket. Geratherm has developed, regarding to effectiveness and handling, smaller blankets than the SOS-Rescue Blanket. The blanket's weight has also been reduced. Thereby, the blankets can be easily folded and require

considerably less storage space, e.g. in rescue vehicles. The control unit of UniqueResc+ is integrated in the blanket. Furthermore, UniqueResc+ has more control safety features than the P.D. With the development of UniqueResc+, appears a very efficient rescue blanket which surface can be heated to approximately 95%. Compared to the predicate device (only 1/3 of the surface is heated) it is an enormous improvement of the performance.

Summary:

The substantial equivalence of the UniqueResc+ R130 and R150 and the referenced and approved earlier warming system, Geratherm SOS-Rescue Blanket (K051097), is based upon substantially similar methods for warming patients.

The predicate device provides warmth to patients through the transmission of heat from the surface of the device to the patient. The R130 and R150 similarly provide the transmission of heat from the surface of the unit to the patient.

The presented data that was conducted on the Geratherm UniqueResc+ shows in its results, and in comparison to the predicate device, 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

Geratherm Medical AG
c/o Mr. Ronald G. LeTourneau
28351 Beck Road, Suite G-5
Wixom, Michigan 48393

SEP 2 0 2010

Re: K093694
Trade/Device Name: Geratherm UniqueResc+
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: II
Product Code: DWJ
Dated: September 13, 2010
Received: September 14, 2010

Dear Mr. LeTourneau:

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

SEP 20 2010

Indication for Use

510(k) Number (if known): K093694

SEP 17 '10

Device Name:
Geratherm UniqueResc[+]

Indications for Use:

Geratherm UniqueResc[+] is a thermal regulating system for adult patients in order to prevent hypothermia in preclinical settings or treatments on-site. It is intended for use while at the rescue scene, during patient transport by air or ground to a medical facility or e.g. during disaster operation in first aid tents. The device should be used by appropriately trained healthcare professionals.

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 K093694