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K963731

APR 22 1997

TRADE NAME: ENTHERMICS TRU-5000™ Thermal Recovery Radiant Heating Unit
COMMON NAME: Thermal Recovery System
CLASSIFICATION NAME: Thermal Regulating System

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) Summary of Safety and Effectiveness Information is being submitted in accordance with the requirements of SMDA 1990. This statement serves to certify that the data and information submitted in this application are truthful and accurate and that no material fact has been omitted.

The function of the ENTHERMICS TRU-5000™ Thermal Recovery Radiant Heating Unit is to provide a safe yet effective means of patient rewarming in the recovery of adult hypothermic human subjects. The TRU-5000 consists of (1) an aesthetically pleasing fiberglass exterior encasing the semi-cylindrical heating chamber, (2) a modified heat resistant stretcher with a unique lock and key design, (3) a stand-alone, dual-probe, skin temperature audible-alarm system and (4) standard hospital sheets used as insulating drapes. An easy to operate control panel provides quick and easy control of all rewarming operations. The control system includes an LED readout of chamber control temperature, two independent skin temperatures and control setpoint with an audible alarm which sounds whenever the skin temperature setpoint is exceeded. The heating surface temperature controller of the TRU-5000 is factory preset at 70 °C to minimize operator error and provide optimum patient warming. The system requires no additional power demands and includes self diagnostic features to ensure operational accuracy. Quick and easy access to the heating chamber is devised in case of medical intervention. The use of the TRU-5000 is a physician prescribed therapy for surgically- or trauma-induced hypothermia, with the ultimate responsibility of the patients overall recovery falling on the physician.

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The ENTHERMICS TRU-5000 Thermal Recovery Radiant Heating Unit is identical in function to the Augustine Medical Bair Hugger™ Convective Warming System (K873745) and the Marquest Temp Marq™ Convective Warming System (K904690) in that it offers a rapid, accurate, reproducible means of administering external heat to adult hypothermia patients in a clinical environment. The aforementioned predicate devices are two "Thermal Regulating Systems" (21 CFR 870.5900) currently used in the area of clinical hypothermic recovery. Thermal Regulating Systems have been evaluated by the Cardiovascular Device Classification Panel and have been labeled as Class II devices.

The ultimate safety and effectiveness of a recovery aid can only be measured by the successful use or misuse of the device. However, the ENTHERMICS TRU-5000 has been designed to provide maximum control and efficiency of patient heating while minimizing the possibility of thermal injury such that the historical standards of safety and effectiveness set forth by the stated predicate devices can be met or exceeded.



Ms. Karen Hansen
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9.10.96

Date