K123309

FEB 05 2013

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	October 23, 2012
Submitter:	Ohmeda Medical, a Division of Datex-Ohmeda, Inc., A General Electric Company 8880 Gorman Rd. Laurel, MD 20723
Primary Contact Person:	Agata Anthony 8880 Gorman Rd. Laurel, MD 20723 Tel: 410-456-0329 Fax: 410 888 0544
Secondary Contact Person:	Kenny M Bello 8880 Gorman Rd. Laurel, MD 20723 Tel: 410-888-5393 Fax: 410 888 0544
Device: Trade Name:	Giraffe and Panda Warmers
Common/Usual Name:	Infant Warmer
Classification Names:	Warmer, Infant Radiant
Product Code:	FMT 880.5130
Predicate Device(s):	Giraffe and Panda Warmers; K122267, K101804, K090697, K072157, K070377
Device Description:	The Giraffe and Panda Warmers are devices with a radiant heating source intended to maintain the thermal balance of an infant patient by direct radiation of energy in the infrared region of the electromagnetic spectrum. The warmers operate similarly to warmers currently in use in hospitals. Radiant heat from an infrared heat source is focused onto the bed to warm the patient. The operator may select either the heater power or skin temperature control method. Depending on the control method selected, the heater is either regulated at the operator selected power level or the heater output is modulated to maintain the patient's temperature at the value selected by the operator. Infant radiant warmers are also used to provide thermal support during surgical procedures and during procedures such as extracorporeal membrane oxygenation, resuscitation, or other procedures requiring open access and thermal support. The units also feature optional integrated SpO_2 and Resuscitation modules. The Resuscitation Module may feature either

a traditional bag-and-mask technology or a T-piece technology. Both the SpO_2 module and the Resuscitation Modules use existing technology. The Giraffe and Panda Warmers can be used with the Giraffe

Shuttle and UPS, a mobile power source that allows for transport of the patient between care areas within the hospital building and provides power to the Warmers.

Description of Device Modification

The proposed modification to Panda branded configuration of the Giraffe and Panda Warmer product line is the expansion of the current product line to offer additional configurations which are identified as Freestanding and Wall Mount. These configurations remove the bed from the predicate Panda branded configuration of the Giraffe and Panda Warmer product line allowing use in commercially available bassinets.

The Freestanding Warmer and the Wall Mount Warmer configurations of the Giraffe and Panda warmers product line are non-bedded with one mounting directly to a wall and the other freestanding on a wheeled base. The two new configurations provide heat to a patient using the same patient temperature control algorithm previously cleared per 510(k) K090697. The Maximum heater output has been reduced to support use of tall bassinets. The predicate resuscitation system will not be available for the Wall Mount configuration. The indication for use of the legally marketed device will remain unchanged with the addition of Freestanding and Wall Mount configurations to the current Giraffe and Panda Warmers product line.

Indication for Use: Infant radiant warmers provide infrared heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. Infant radiant warmers may be used to facilitate the neonate's transition to the external environment or to provide a controlled open environment. An optional integrated SpO_2 monitoring feature may be used for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). An optional integrated resuscitation system may be used to provide the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the infant.

Device Modification The Freestanding and Wall Mount warmer configurations will

Technology: utilize the existing Panda branded Warmer head, operator interface display, pulse oximetry technologies and resuscitation (Freestanding only). The fundamental technologies in use in the warmer have not been changed by the proposed modification

Device Modifications include software and mechanical changes.

Software was changed to support these configurations in two basic areas. First is scaling back the actual heater power at any given input level to comply with standards requirements for surface touch temperatures at maximum altitude (10,000 ft.), maximum ambient operating temperature (30 °C) and with the tallest specified bassinet (39" from floor to bed surface). The second software change is the adoption of a proportional heater control algorithm described in the Giraffe and Panda warmer 510k (K090697).

Mechanical changes include new rails and new wheeled base for the Freestanding unit. The Wall Mount unit requires new rails, a wall mounting bracket, and a new filler plate between the probe panel and the display.

The proposed modification does not change the indication for use of the legally marketed product.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Giraffe and Panda Warmers product line and its applications comply with voluntary standards. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, the Freestanding and Wallmount configurations of the Giraffe and Panda Warmers product line, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Freestanding and Wallmount configurations of the Giraffe and Panda Warmers product line to be as safe, as effective, and equivalent in performance to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 5, 2013

Mr. Kenny M. Bello
Regulatory Affairs Leader
Ohmeda Medical
Division of Datex-Ohmeda, Incorporated
General Electric Healthcare Company
8880 Gorman Road
Laurel, Maryland 20723

Re: K123309
Trade/Device Name: Giraffe and Panda Warmers
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: II
Product Code: FMT
Dated: January 7, 2013
Received: January 9, 2013

Dear Mr. Bello:

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.

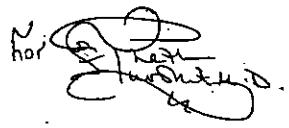
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K123309

Device Name: Giraffe and Panda Warmers

Indications for Use:

Infant radiant warmers provide infrared heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. Infant radiant warmers may be used to facilitate the neonate's transition to the external environment or to provide a controlled open environment. An optional integrated SpO_2 monitoring feature may be used for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). An optional integrated resuscitation system may be used to provide the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the infant.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 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)

Digitally signed by Richard C. Chapman
Date: 2013.02.01 11:41:50 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123309