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## GE Healthcare

Special 510(k) Premarket Notification Submission **JUL 21 2010**  
**510(k) Summary**

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

Date: June 23, 2010

Submitter: Ohmeda Medical, a Division of Datex-Ohmeda, Inc., A General Electric Company

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Laurel, MD 20723

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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

Device and Change Legally Marketed 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. Both units also feature optional integrated SpO2 and Resuscitation Modules. The Resuscitation Module may feature either a traditional bag-and-mask



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technology or a T-piece technology.

The Giraffe and Panda Uninterruptible Power Supply (UPS) provides a short term source of electrical power to the Warmers, thus aiding their intra hospital mobility. The power cord of the Giraffe and Panda Warmer devices is plugged into Giraffe and Panda UPS, and, in turn, the power cord of the UPS is then connected to the wall receptacle. When disconnected from wall power, the parent device continues receiving the power that it needs to operate, but the energy is supplied by the UPS rather than the distribution line.

The UPS does not change the indications for use, control mechanisms, operating principles, performance specifications, or other features of the Giraffe and Panda Warmers. The UPS serves as an extension to the Warmers by providing uninterrupted electric power to the device. The UPS comprises a medical grade battery and a shelf.

When used with the UPS, the Giraffe and Panda Warmers are not intended for use as transport incubator or to be taken outside of the hospital building.

### Description of Device Modification

The proposed modification of the Giraffe and Panda Warmers is the addition of the Giraffe Shuttle accessory.

The Giraffe and Panda Warmers can be used with the Giraffe Shuttle, a mobile power source that allows for transport of the patient between care areas within the hospital building and provides power to the Warmers. These areas include, but are not limited to Labor and Delivery, NICU, Radiology, and Operating Room.

This eliminates the need to transfer the infant to and from a transport incubator for transport within the hospital building, reducing the potential for clinical problems associated with patient touch, handling and movement. The patient can instead be moved within the hospital in a single device. This reduces the potential for clinical problems associated with intra-hospital transport that result from interrupted patient thermal regulation.

Similarly to the UPS accessory, the Shuttle facilitates the mobility of the Giraffe and Panda Warmers within the hospital building. The Warmers, when used with the UPS or with the Shuttle are not a transport incubator and are not intended to be used outside of the



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hospital building.

The Shuttle has two primary active functions: Locking to a bed and providing transportable power to the bed and accessories.

Attaching the Shuttle to a bed is accomplished by guiding the Shuttle between the legs of the bed and stepping on the Lock pedal. This effectively locks the Shuttle and bed together as one unit.

To detach the Shuttle from the bed, the locking arms are rotated back to their unlocked position by stepping on the Unlock pedal. Once unlocked, the Shuttle can be moved away from the bed.

The internal power source of the Shuttle consists of two 12 volt 42 amp hour lead acid batteries. The batteries are high capacity, sealed, no-maintenance batteries and are connected in series to provide a nominal 24 volts supply to the power generation module.

### Legally Marketed Device Intended Use:

The intended use of the legally marketed device and the proposed modified device is identical. The intended use is as follows:

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 SpO2 monitoring feature may be used for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 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 Technology:

The Giraffe Shuttle is a transportable power source that is an accessory to the Giraffe and Panda Warmers. The Shuttle connects to the Warmer and provides electrical power to the bed and other auxiliary equipment, required for patient care during transport.

The Shuttle is configured to attach to the Giraffe and Panda Warmers and provide electrical power to the bed and selected accessories. The Shuttle makes it possible to deliver continuous baby care during



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transport from one hospital area to another (e.g. from L&D to NICU).

The Shuttle is designed to accept all Shuttle-specific accessories from GE Healthcare, including: the cord wrap bracket and gas cylinder holder.

The Shuttle has two primary active functions: Locking to a bed and providing transportable power to the bed and accessories.

The Shuttle contains two sensor systems:

- One system detects an interference condition.
- The other system determines the attaching status of the device.

The Shuttle features an LED Display Board, which contains the battery runtime indicator and the battery health indicator.

### Determination of Substantial Equivalence:

#### Summary of Non-Clinical Tests:

The Giraffe and Panda Warmers and their applications with the Giraffe Shuttle, comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

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

#### Clinical Tests:

The subject of this premarket submission, Giraffe and Panda Warmers, used with Shuttle, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the modified Giraffe and Panda Warmers, used with the Giraffe Shuttle accessory to be as safe, and effective,



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

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Ms. Agata Smieja  
Regulatory Affairs Director  
OHMEDA Medical, a Division of Datex-OHMEDA, Incorporated, A General Electric  
Company  
8880 Gorman Road  
Laurel, Maryland 20723

Re: K101804  
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: June 23, 2010  
Received: June 28, 2010

Dear Ms. Smieja:

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,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



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510(k) Number (if known): K101804

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 Spa 2 monitoring feature may be used for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by a SpO2 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  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use     
(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)

(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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