

**510(k) Summary**

AUG 27 2007

Submitter Information and Date Prepared

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Prepared August 24, 2007

Device Identification

Proprietary Name: Ohmeda Medical Giraffe and Panda Warmers  
Common Name: Giraffe and Panda Warmers

Predicate Device Information

Predicate Device	510(k) Number
Giraffe and Panda Warmers	K070377

Intended Use Statement

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 SP02 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.

#### Functional Description and Technological Characteristics

The Ohmeda Medical 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 technology or a T-piece technology. Both the SpO2 module and the Resuscitation Modules use existing technology.

Infant radiant warmers may incorporate other features, such as tilting of the bed, elevating base, and data output to remote monitors or nurse call systems. Infant radiant warmers may also allow use with or attachment of an independent phototherapy device or other accessories.

The Giraffe and Panda UPS is a stand-by power supply that will serve the purpose of temporarily maintaining the operation of the parent devices, the Giraffe and Panda Warmers. Instances where normal line supply is interrupted include but are not limited to:

- 1) power failure due to brown/black out scenario
- 2) unintentional disconnect of parent device power cord from wall receptacle
- 3) purposeful disconnect from wall receptacle of the parent device to affect short duration, intra-hospital transport of the parent device

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 comprises a medical grade battery and a shelf.

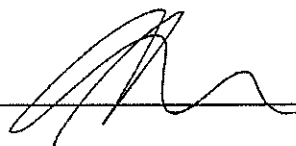
#### Performance Data

Because care of infants in infant radiant warmers is a well established clinical practice and because the Giraffe and Panda Warmer will comply with all applicable clauses of the recognized consensus standard for infant radiant warmers, animal or clinical testing to support safety and effectiveness is not necessary. The conformance of the Giraffe and Panda Warmers to performance specifications and to multiple recognized performance standards is being established through bench testing.

The UPS battery has a life of 20 minutes in nominal operating conditions (60% heater power), 15 minutes at the worst case operation condition (100% heater power) and 10 minutes at the worst case operating condition with the addition of the phototherapy accessory and with all available lights on (at 100% heater power). The recharge time is 6 hours.

Performance of the Giraffe and Panda Warmers with the addition of UPS has been established by bench testing against product specifications and recognized consensus standards.

Prepared by:



Date 08/24/07



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 27 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Agata Smieja  
Global Compliance Leader  
Ohmeda Medical, a Division of Datex Ohmeda, a GE Healthcare Company  
8880 Gorman Road  
Laurel, Maryland 20723

Re: K072157  
Trade/Device Name: Giraffe and Panda Warmer  
Regulation Number: 21 CFR 880.5130  
Regulation Name: Infant Radiant Warmer  
Regulatory Class: II  
Product Code: FMT  
Dated: August 2, 2007  
Received: August 3, 2007

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K072157

Device Name: Giraffe and Panda Warmer

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 SpO2 monitoring feature may be used for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SP02 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.

For professional use only, by trained clinicians.

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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K072157