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510(k) Summary

JUL 11 2007

Submitter Information and Date Prepared

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8880 Gorman Road
Laurel, MD 20723
USA

410-888-5218

Prepared June 18, 2007

Device Identification

Proprietary Name:	Giraffe and Panda Warmer
Common Name:	Infant Radiant Warmer
Classification Name:	Warmer, Infant Radiant (21 CFR 880.5130)

Predicate Device Information

The Giraffe and Panda Warmer is substantially equivalent to the following predicate devices:

Predicate Devices	510(k) Number
Ohmeda Medical Infant Warmer System (IWS) Model 4300	K963058
Ohmeda Medical OmniBed (in open mode)	K993407
Masimo SET technology SpO2	K033296
Atom Infa Warmer V505	K002355
Giraffe and Panda T-piece Resuscitation System	K070210
Giraffe and Panda Bag and Mask Resuscitation System	K070247

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

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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.

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.

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

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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.

Prepared by: _____ Date _____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2007

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

Re: K070377
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: July 2, 2007
Received: July 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): K070377

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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