K090697

510(k) Summary

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

Date:	March 16, 2009
Submitter:	Ohmeda Medical/GE Healthcare 8880 Gorman Rd Laurel, MD 20723, USA
Primary Contact Person:	Agata Smieja Regulatory Affairs Manager Ohmeda Medical/GE Healthcare Tel: 410 456 0329 Fax: 410 888 0544
Secondary Contact Person:	Andrew Ahn GE Healthcare Regulatory Affairs Leader Ohmeda Medical/GE Healthcare Tel: 410 888 5332 Fax: 410 888 0544
Device: Trade Name:	Giraffe and Panda Warmer
Common/Usual Name:	Infant radiant warmers
Classification Names:	21 CFR 880.5130
Product Code:	FMT
Predicate Device(s):	Giraffe and Panda Warmers (K072157, K070377)
Device Description:	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.
Intended 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.

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For professional use only, by trained clinicians.

Technology: The Giraffe and Panda Warmers employ the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Giraffe and Panda Warmer and its applications comply with voluntary standards as detailed in this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Review
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

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

Conclusion: GE Healthcare considers the Giraffe and Panda Warmers to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Agata Smieja
Regulatory Affairs Manager
Ohmeda Medical/GE Healthcare
8880 Gorman Road
Laurel, Maryland 20723

APR 16 2009

Re: K090697
Trade/Device Name: Giraffe and Panda Warmers
Regulation Number: 21 CFR 880.5130
Regulatory Class: II
Product Code: FMT
Dated: March 16, 2009
Received: March 17, 2009

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

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 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.

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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)

For ABC Scott Colburn 04/15/09

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

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