K071175

JUL 17 2007

510(k) Summary

Submitter Information and Date Prepared

Agata Smieja
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8880 Gorman Road
Laurel, MD 20723
USA

Phone: 410 888 5218
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Prepared July 16, 2007

Device Identification

Proprietary Name: Ohmeda Medical Giraffe OmniBed
Common Name: Giraffe OmniBed

Predicate Device Information

Predicate Device	510(k) Number
Ohmeda Medical Giraffe OmniBed	K993407
Ohmeda Medical Giraffe OmniBed (with optional Servo Controlled Oxygen Delivery System)	K020543

Intended Use Statement

The OmniBed is a combination of an infant incubator and an infant warmer. The device can be operated as an incubator or as a warmer and can transition from one mode to the other on user's demand. It cannot be operated in both modes at the same

time. Incubators and warmers provide heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. Incubators provide an enclosed, temperature-controlled environment and warmers provide infrared heat in an open environment. They may also be used for short periods of time to facilitate the neonate's transition from the uterus to the external environment.

This device may incorporate a Servo Controlled Oxygen Delivery System. This is indicated to provide stable oxygen concentration within the infant compartment at the value set by the operator (21-65%).

Functional Description and Technological Characteristics

Giraffe OmniBed is an infant bed, which provides thermal support to infants who are unable to thermo-regulate based on their own physiology. The bed has two modes of operation, enclosed bed operation and open bed operation. In an open mode, the device functions as an incubator and in an enclosed mode it functions as a conventional, infant radiant warmer.

Functional description of the new features added to the device

The Giraffe Uninterruptible Power Supply (UPS) is intended to provide a short term source of electrical power Giraffe OmniBed, thus aiding its intra hospital mobility. The Giraffe UPS does not change the indications for use, control mechanisms, operating principles, performance specifications, or other features of the Giraffe Omnibed.

The UPS serves as an extension to the Giraffe OmniBed by providing uninterrupted electric power to the device. The UPS comprises a medical grade battery and a shelf.

Performance Data

The battery has a life of 15 minutes at 37° C and 70% RH at steady state. The recharge time is 6 hours.

The addition of the UPS to the Giraffe OmniBed reduces the decibel level of the alarm at 3 meters in front of the equipment by less than 1 dB, within the minimum lower level of 50dB as specified by IEC 601-2-21 Amend 1 clause 102.1 and IEC-601-2-19 Amend 1 clause 102.3.

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

Prepared by: _____ Date _____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2007

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

Re: K071175
Trade/Device Name: Giraffe OmniBed
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ
Dated: June 28, 2007
Received: June 29, 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.

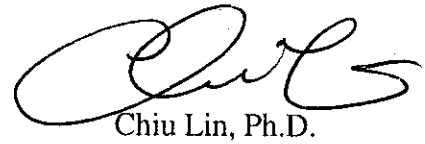
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K071175

Device Name: Giraffe OmniBed

Indications for Use:

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Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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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510(k) Number: K071175