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510(k) Summary

OCT 3 2007

Submitter Information and Date Prepared

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USA

Phone: 410 888 5218
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Prepared: September 4, 2007

Device Identification

Proprietary Name: Ohmeda Medical Giraffe Incubator
Common Name: Giraffe Incubator

Predicate Device Information

Predicate Device	510(k) Number
Giraffe Incubator	**K020547**

Intended Use Statement

The Giraffe Incubator is an Infant Incubator. Incubators provide heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. They achieve this by providing an enclosed temperature controlled environment to the infant. This device may incorporate a Servo Controlled Oxygen Delivery System. This is indicated to provide a stable oxygen concentration within the infant compartment at the value set by the operator (21-65%)

Product Description

The Ohmeda Medical Giraffe Incubator is an infant bed which provides thermal support for infants who are unable to provide for their own heat requirements. The device manintains the infant's temperature by circulating heated air within the enclosed bed compartment. The operator may select either the air or skin temperature control method. Depending on the control method selected, heat is regulated based on either the air temperature or the infant's skin temperature compared to the operator selected control temperature. Physical access to the patient is obtained through the side portholes or by opening one of the side doors. The optional Giraffe Servo Control Oxygen Delivery System is a fully integrated option available on the Giraffe Incubator. The Giraffe Servo Control Oxygen Delivery System is capable of oxygenating the entire infant compartment at oxygen concentrations of 21%-65% by volume. The device uses fuel cell type sensors that generate specific voltages depending on the oxygen concentrations they contact. The microprocessor stores the sensor output and compares it with the value corresponding to the concentration set by the operator. The valves that supply oxygen to the infant compartment are opened and closed as necessary to maintain the oxygen concentration at the set value. Fluctuations in fuel cell performance due to temperature and humidity are are compensated for by the microprocessor.

The Giraffe and Panda Uninterruptible Power Supply (UPS) provides a short term source of electrical power Giraffe Incubator, 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 Incubator.

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

Performance Data

Since care of newborns in incubators, with or without supplemental oxygen, is a well established clinical practice, Ohmeda submits that clinical or animal testing to demonstrate safety and effectiveness is not necessary. The product was subject to extensive bench testing, the software was validated and, to the best of Ohmeda Medical's knowledge, the requirements of 21 CFR 820, Subpart C-Design Controls were satisfied.

The UPS battery has a life of 15 minutes in nominal operating conditions (37C, 70% RH), 10 minutes at the worst case operation condition (39C, 95% RH) and 7 minutes at the worst case operating condition with the addition of the phototherapy accessory and with all available lights on (39C, 95% RH) . The recharge time is 6 hours.

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

Prepared by: _____ Date 09/04/07

AGATA SMIEJA

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Ms. Agata Smieja
Global Compliance Leader
Datex-Ohmeda, Incorporated
A Division of Datex Ohmeda, A GE Healthcare Company
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Laurel, Maryland 20723

OCT 3 2007

Re: K072512
Trade/Device Name: Ohmeda Medical Giraffe Incubator
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ
Dated: September 4, 2007
Received: September 6, 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

K072512

Indications for Use

510(k) Number (if known): K 072512

Device Name: Ohmeda Medical Giraffe Incubator

Indications For Use:

The Giraffe Incubator is an Infant Incubator. Incubators provide heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. They achieve this by providing an enclosed temperature controlled environment to the infant. This device may incorporate a Servo Controlled Oxygen Delivery System. This is indicated to provide a stable oxygen concentration within the infant compartment at the value set by the operator (21-65%)

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

510(k) Number: K072512

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