K101778
1 of 4

JUL 21 2010

GE Healthcare

Special 510(k) Premarket Notification Submission

510(k) Summary

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

Date:	June 17 2010
Submitter:	Ohmeda Medical, a Division of Datex-Ohmeda, Inc., A General Electric Company 8880 Gorman Rd. Laurel, MD 20723
Primary Contact Person:	Agata Smieja 8880 Gorman Rd. Laurel, MD 20723 Tel: 410-456-0329 Fax: 410 888 0544
Secondary Contact Person:	Andrew Ahn 8880 Gorman Rd. Laurel, MD 20723 Tel: 410-888-5332 Fax: 410 888 0544
Device: Trade Name:	Giraffe Incubator
Common/Usual Name:	Incubator
Classification Names:	Incubator, Neonatal: FMZ (880.5400)
Product Code:	
Predicate Device(s):	Giraffe Incubator Legally Marketed Device
Device and Change Description:	The Giraffe Incubator is an infant bed, which provides thermal support for infants who are unable to provide for their own heat requirements. The device maintains 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 compensated for by the microprocessor.

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

When used with the UPS, the Giraffe Incubator is not intended for use as transport incubator or to be taken outside of the hospital building.

Description of Device Modification

The proposed modification of the Giraffe Incubator is the addition of the Giraffe Shuttle accessory.

The Giraffe Incubator can be used with the Giraffe Shuttle, a mobile power source that allows for transport of the patient between care areas within the hospital building and provides power to the Incubator. These areas include, but are not limited to Labor and Delivery, NICU, Radiology, and Operating Room.

This eliminates the need to transfer the infant to and from a transport incubator for transport within the hospital building, reducing the potential for clinical problems associated with patient touch, handling and movement. This reduces the potential for clinical problems associated with intra-hospital transport that result from interrupted patient thermal regulation. .

Similarly to the UPS accessory, the Shuttle facilitates the mobility of the Giraffe Incubator within the hospital building. Giraffe Incubator when used with the UPS or with the Shuttle is not a transport incubator and is not intended to be used outside of the hospital building.

The Shuttle has two primary active functions: Locking to a bed and

providing transportable power to the bed and accessories.

Attaching the Shuttle to a bed is accomplished by guiding the Shuttle between the legs of the bed and stepping on the Lock pedal. This effectively locks the Shuttle and bed together as one unit.

To detach the Shuttle from the bed, the locking arms are rotated back to their unlocked position by stepping on the Unlock pedal. Once unlocked, the Shuttle can be moved away from the bed.

The internal power source of the Shuttle consists of two 12 volt 42 amp hour lead acid batteries. The batteries are high capacity, sealed, no-maintenance batteries and are connected in series to provide a nominal 24 volts supply to the power generation module.

Legally Marketed Device Intended Use:

The intended use of the legally marketed device and the proposed modified device is identical. The intended use is as follows:

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%).

Device Modification Technology:

The Giraffe Shuttle is a transportable power source that is an accessory to the Giraffe Incubator. The Shuttle connects to the bed and provides electrical power to the bed and other auxiliary equipment, required for patient care during transport.

The Shuttle is configured to attach to the Giraffe Incubator and provide electrical power to the bed and selected accessories. The Shuttle makes it possible to deliver continuous baby care during transport from one hospital area to another (e.g. from L&D to NICU).

The Shuttle is designed to accept all Shuttle-specific accessories from GE Healthcare, including: the cord wrap bracket and gas cylinder holder.

The Shuttle has two primary active functions: Locking to a bed and providing transportable power to the bed and accessories.

The Shuttle contains two sensor systems:

- One system detects an interference condition.
- The other system determines the attaching status of the device.

The Shuttle features an LED Display Board, which contains the battery runtime indicator and the battery health indicator.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Giraffe Incubator and its applications with the Giraffe Shuttle, complies with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Usability testing (Validation)
- Biocompatibility testing

Clinical Tests:

The subject of this premarket submission, Giraffe Incubator used with Shuttle, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the modified Giraffe Incubator, used with the Giraffe Shuttle accessory to be as safe, as effective, and performance is substantially equivalent to the legally marketed Giraffe Incubator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 21 2010

Mr. Agata Smieja
Regulatory Affairs Director
OHMEDA Medical
8880 Gorman Road
Laurel, Maryland 20723

Re: K101778
Trade/Device Name: Giraffe Incubator
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ
Dated: June 17, 2010
Received: June 25, 2010

Dear Mr. 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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GE Healthcare

Special 510(k) Premarket Notification Submission

510(k) Number (if known): [INSERT 510(k) NUMBER IF KNOWN] K101778

Device Name: 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) (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)

7/9/10

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

510(k) Number: K101778