



Food and Drug Administration
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March 17, 2016

Ohmeda Medical
A Division of Datex-ohmeda, Inc., A GE Company
Mr. Kenny Bello
Regulatory Affairs Leader
8880 Gorman Road
Laurel, Maryland 20723

Re: K152814
Trade/Device Name: Giraffe Omnibed Carestation CS1
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ, FMT
Dated: February 18, 2016
Received: February 19, 2016

Dear Mr. Bello:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

 Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152814

Device Name
Giraffe Omnibed Carestation CSI

Indications for Use (Describe)

The Giraffe OmniBed Carestation 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%).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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

Date: 18 FEB 2016

Submitter: Ohmeda Medical, a Division of Datex-Ohmeda, Inc., A General Electric Company

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Regulatory Affairs Director

Ohmeda Medical, a Division of Datex-Ohmeda, Inc., A General Electric Company

Device Trade Name: Giraffe OmniBed Carestation CS1

Common/Usual Name: Incubator / Warmer

Classification Names: Incubator, Neonatal: (880.5400)

Regulatory Class II

Product Code: FMZ, FMT

Predicate Device(s): Giraffe OmniBed, K101788, K071175 K020543, K993407

Device Description: The Giraffe OmniBed Carestation is an updated version of the cleared predicate Giraffe OmniBed. The Giraffe OmniBed Carestation is a combination device that can function as an incubator (with the canopy closed) or as an infant radiant warmer (with the canopy open) based on the user's selection.

Incubators and warmers provide heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. With the canopy closed, the bed functions as an incubator, maintaining 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 operated selected control temperature. Physical access to the patient is obtained through the side portholes or by opening one of the side doors.

With the canopy opened, this bed operates like a conventional open, radiantly heated infant bed. Radiant heat from an infrared heat source is focused onto the bed to warm the patient.

The Giraffe OmniBed Carestation incorporates an optional weighing scale, Uninterruptible Power Supply (UPS) & Shuttle, Mounting Accessories Rail and Shelves and Storage drawers.

Description of Device Modification

The proposed modification of the Giraffe OmniBed is referred to as the Giraffe OmniBed Carestation.

The Giraffe OmniBed Carestation updates the graphical monochrome display user interface (UI) on the predicate to a digital touchscreen UI, with the required software changes to support the new format and layout. The main system control software was not changed; however the software for the UI was updated because of the UI format change. The modified Giraffe OmniBed Carestation maintains the predicate Giraffe OmniBed functionality, performance, and clinical workflows. The changes also include a modified device visual indicator light and the capability for Hands Free Alarm Silencing (HFAS).

Other modifications being made for the Giraffe OmniBed Carestation include upgrading the power supply from 75W to 120W to support the increased power requirements of the touchscreen and associated electronics.

There is no change in the indications for use or intended use of the system. There are no changes to the patient contacting materials of the device, and they remain identical to the predicate. The changes made do not affect the function, performance, safety, or clinical use of the device.

Indication for Use:

The Giraffe OmniBed Carestation 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%).

Device Modification Technology:

The Giraffe OmniBed Carestation employs the same fundamental scientific technology as its predicate device.

The Giraffe OmniBed Carestation replaces the Graphic Display of the current



Giraffe OmniBed (GOB) with a new design based on a Single Board Computer (SBC), color LCD, and touch screen. The Graphical User Interface (GUI) incorporates graphical elements that are compatible with current Giraffe functionality and workflow. The information displayed to the user and the device functionality/features are equivalent, with a different layout and touch screen functionality.

The existing 75W power supply was replaced with a 120W part because the new interface has a higher power requirement than the predicate unit's graphical monochrome display interface.

The Giraffe OmniBed Carestation also introduces an updated device Indicator light and Hands Free Alarm Silence (HFAS) capability.

Determination of Substantial
Equivalence and performance
Data:

Summary of Non-Clinical Tests:

The Giraffe OmniBed Carestation is an updated version of the cleared predicate Giraffe OmniBed; K101788, K071175, K020543, K993407. It complies with voluntary standards and the following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Software testing (Verification and Validation, IEC 62304:2006 – Medical Device Software - Software life cycle processes)
- Performance testing (Verification of performance specifications, including IEC 60601-2-21:2009 - Particular requirements for the safety of infant radiant warmers , IEC 60601-2-19:2009 - Particular requirements for the safety of incubators)
- Safety and EMC testing (Verification ES 60601-1:2005+A1 2012 - General Requirements for Safety, IEC60601-1-2:2007 - Electromagnetic compatibility - Requirements and tests))
- Usability testing (Validation IEC 62366: 2014 - Application of usability engineering to medical devices)

The testing performed to support these modifications was based on the risk assessment and design controls, and summary level data was provided in the 510(k) for the testing described above.

Summary of Clinical Tests:

The subject of this premarket submission, Giraffe OmniBed Carestation, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Giraffe OmniBed Carestation to be as safe, as effective, and the performance to be substantially equivalent to the predicate device.