DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 31, 2015

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

Re: K152809
Trade/Device Name: Giraffe Incubator Carestation CS1
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ
Dated: November 25, 2015
Received: November 27, 2015

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152809

Device Name
Giraffe Incubator Carestation CSI

Indications for Use *(Describe)*
The Giraffe Incubator Carestation 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%).

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:	23 DEC 2015
Submitter:	Ohmeda Medical, a Division of Datex-Ohmeda, Inc., A General Electric Company 8800 Gorman Road Laurel, MD 20723 Tel: (410)888-5200 Fax: (410)888-0544
Primary Contact Person:	Kenny M Bello Regulatory Affairs Leader Ohmeda Medical, a Division of Datex-Ohmeda, Inc., A General Electric Company Tel: (410) 888-5393 Fax: (410) 888-0544
Secondary Contact Person:	Monica Morrison Regulatory Affairs Director Ohmeda Medical, a Division of Datex-Ohmeda, Inc., A General Electric Company
Device Trade Name:	Giraffe Incubator Carestation CS1
Common/Usual Name:	Incubator
Classification Names:	Incubator, Neonatal: (880.5400)
Regulatory Class	II
Product Code:	FMZ
Predicate Device(s):	Giraffe Incubator; K101778, K072512, K020547, K010222
Device Description:	The Giraffe Incubator Carestation is an updated version of the cleared predicate Giraffe Incubator. The Giraffe Incubator Carestation is an enclosed 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 closed 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 Giraffe Incubator 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 Incubator is referred to as the Giraffe Incubator Carestation.

The Giraffe Incubator 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 Incubator Carestation maintains the predicate Giraffe Incubator 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 Incubator 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 Incubator Carestation 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 Incubator Carestation employs the same fundamental scientific technology as its predicate devices.

The Giraffe Incubator Carestation replaces the Graphic Display of the current Giraffe Incubator (GINC) 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 have a higher power budget than the predicate unit’s

graphical monochrome display interface.

The Giraffe Incubator 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 Incubator Carestation is an updated version of the cleared predicate Giraffe Incubator; K101778, K072512, K020547, K010222. It complies with voluntary standards and the following quality assurance measures were applied to the development of the system:

- Risk Analysis (ISO 14971)
- Design Reviews (QSR, ISO 13485)
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Software testing (Verification and Validation IEC 62304, "moderate" level of concern)
- Performance testing (Verification of performance specifications, including IEC 60601-2-19)
- Safety and EMC testing (Verification ES 60601-1, IEC60601-1-2)
- Usability testing (Validation IEC 62366)

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 Incubator Carestation, did not require clinical studies to support substantial equivalence.

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