March 2, 2022

Datex Ohmeda Inc.
Shiwani Zalpuri
Regulatory Affairs Leader
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K213551
Trade/Device Name: Giraffe Omnibed Carestation CS1
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: Class II
Product Code: FMT, FMZ
Dated: January 28, 2022
Received: January 31, 2022

Dear Shiwani Zalpuri:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gang Peng for
Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Giraffe Omnibed Carestation CS1

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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In accordance with 21 CFR 807.92 the following summary of information is provided:	
Date:	02-March-2022
Submitter:	Datex-Ohmeda, Inc. 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Shiwani Zalpuri Regulatory Affairs Leader GE Healthcare Phone: +91 9871090801 Email: shiwani.zalpuri@ge.com
Secondary Contact Person:	Lee Bush Regulatory Affairs Director GE Healthcare Phone: 262-309-9429 Email: Lee.Bush@ge.com
Device Trade Name:	Giraffe Incubator Carestation CS1
Common/Usual Name:	Neonatal Incubator
Classification Names:	Neonatal Incubator
Regulation	21 CFR 880.5400 Neonatal Incubator
Classification	II
Product Code:	FMZ
Predicate Device:	Giraffe Incubator (K152809)
Indications 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%).

5.1 Device Description:

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 has a color touchscreen user interface (UI) and includes a Hands-Free Alarm Silence (HFAS) feature. The incubator includes a mattress for patient comfort. The Giraffe Incubator Carestation incorporates an optional weighing scale, Servo O2, Uninterruptible Power Supply (UPS) & Shuttle, Mounting Accessories Rail and Shelves and Storage drawers.

5.2 Comparison of Technological Characteristics with the Predicate Device

The Porthole Latch design has been modified to change the latch action from "press to open" to "turn to open". The design of the latch mounting part was modified to accommodate the redesigned latch. There were no impacts to form, fit or function of the Porthole Door of incubator aside from the latch.

The design of the Wall Latches and latch receptacles on the North side of the device have been modified. A secondary "catch" was added to address the situation where users leave the door vertical/up with the primary latches not engaged. The receptacles and back plates used to secure the latches on the NE and NW side of the wall have also been modified to accommodate the changes to the wall latches. There were no impacts to form, fit or function of the wall of the incubator aside from the latches. See detailed comparison of the proposed device relative to the predicate device in the table below.

Product Comparison with Predicate Device (K152809)

Specification	Predicate Device (K152809) Giraffe Incubator Carestation CS1	Proposed Device Giraffe Incubator Carestation CS1	Discussion of Differences
Indications 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%).	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%).	Identical
Sterility	non-sterile device	non-sterile device	Identical
Display Manual Control	10.4" Color LCD 10.4" Touch Screen	10.4" Color LCD 10.4" Touch Screen	Identical
Alarm Silence	Two Options: • Touch Screen Silence • Hands free Alarm silence (HFAS)	Two Options: • Touch Screen Silence • Hands free Alarm silence (HFAS)	Identical
Device Indicators	White Device Indicator light Updates to alarm display (enhanced presentation on the touch screen, colors) and sounds (tones, volumes, and frequencies) in compliance with IEC 60601-1-8 Power Fail Indicator LED	White Device Indicator light Updates to alarm display (enhanced presentation on the touch screen, colors) and sounds (tones, volumes, and frequencies) in compliance with IEC 60601-1-8 Power Fail Indicator LED	Identical
Environment of use	Labor and Delivery, NICU, Radiology, and Operating Room.	Labor and Delivery, NICU, Radiology, and Operating Room.	Identical
Dimensions	Weight: 138 ± 1 kg Mattress Size: 48.8cm x 64.8cm Height: 152 cm Width: 66 cm Depth: 114 cm	Weight: 138 ± 1 kg Mattress Size: 48.8cm x 64.8cm Height: 152 cm Width: 66 cm Depth: 114 cm	Identical
Bed Tilt	Mattress tilt angle: 12°	Mattress tilt angle: 12°	Identical

Specification	Predicate Device (K152809) Giraffe Incubator Carestation CS1	Proposed Device Giraffe Incubator Carestation CS1	Discussion of Differences
Electrical Power ratings Requirements	11.5 @ 100V ~ 50/60 Hz 9.5A @ 115V ~ 50/60 Hz 5.5A @ 220/230/240V ~ 50/60 Hz	11.5 @ 100V ~ 50/60 Hz 9.5A @ 115V ~ 50/60 Hz 5.5A @ 220/230/240V ~ 50/60 Hz	Identical
Primary Electrical Safety Standards	IEC 60601-1 IEC 60601-2-19 IEC 60601-1-2	IEC 60601-1 IEC 60601-2-19 IEC 60601-1-2	Identical
Humidity	Servo control accuracy: ± 10 % Ramp-up time: <50 minutes Operating time without refill: >12 hours	Servo control accuracy: ± 10 % Ramp-up time: <50 minutes Operating time without refill: >12 hours	Identical
System Performance	Temp Control accuracy: ± 1.0°C (Control Temp vs. Avg. Incubator Temp) Variability: ± 0.5°C (Incubator Temp vs. Avg. Incubator Temp) Warm-up time: < 50 min. (Time to reach 39°C control temp from cold Start) Patient temp measurement accuracy: ± 0.3°C @ 30°C to 42°C (Accuracy of patient temperature Measurement) Air Velocity: <10 cm/sec CO2 level: 0.3% Maximum CO2 level measured per IEC 60601-2-19 Sound level < 50 dbA Alarms associated with key performance items	Temp Control accuracy: ± 1.0°C (Control Temp vs. Avg. Incubator Temp) Variability: ± 0.5°C (Incubator Temp vs. Avg. Incubator Temp) Warm-up time: < 50 min. (Time to reach 39°C control temp from cold Start) Patient temp measurement accuracy: ± 0.3°C @ 30°C to 42°C (Accuracy of patient temperature Measurement) Air Velocity: <10 cm/sec CO2 level: 0.3% Maximum CO2 level measured per IEC 60601-2-19 Sound level < 50 dbA Alarms associated with key performance items	Identical
User Control Settings	• Patient control temperature 35- 37.5°C in 0.1° increments • Air control temperature 20-39°C in 0.1 increments • Humidity Servo - % relative humidity 30-95% in 5% increments	• Patient control temperature 35- 37.5°C in 0.1° increments • Air control temperature 20-39°C in 0.1 increments • Humidity Servo - % relative humidity 30-95% in 5% increments	Identical

Specification	Predicate Device (K152809) Giraffe Incubator Carestation CS1	Proposed Device Giraffe Incubator Carestation CS1	Discussion of Differences
Port Hole Latches	User action is to Press the Latch toward the incubator to open the Port hole door. The Latch design allows clinical user to push the door closed.	User action to open the Port hole door is to Rotate the Knob Clockwise or Counterclockwise. The Latch design allows user to turn the Port Hole Latch or Knob to close the Port Hole Door.	Different. The porthole latch now utilizes rotate to open action instead of press to open. The Port hole functionality and device performance remains the same and does not raise different questions of safety and effectiveness.
Wall Latches	East Side Wall & West Side wall have two wall latches, one on South side and one on North side. The Wall latch assembly is common for all 4 side North East Side, North West Side, South East Side, and South West Side. Each Latch assembly contains one Latching point which is operated via pinch to open mechanism.	East Side Wall & West Side wall have two Wall latches, one on South side and one on North side. The South side wall latches are common and unchanged from the predicate. North side latches each have two latching points, a primary latch and secondary latch. All latches are operated via pinch to open mechanism which is unchanged from the predicate.	Similar. The secondary latching mechanism provides additional secondary catch mechanism. The functionality of the latches to secure the side panels and the pinch to open operation remain unchanged and meet all performance and standards requirements.
Operating Environment	Temperature: 20° to 30° C Humidity: 10 to 95% RH (non- condensing) Air Velocity: Up to 0.3 m/sec	Temperature: 20° to 30° C Humidity: 10 to 95% RH (non- condensing) Air Velocity: Up to 0.3 m/sec	Identical
Mattress Cover Material	• Polyurethane Laminated Fabric • Silkscreened GE branding logo ink type	• Polyurethane Laminated Fabric • Silkscreened GE branding logo ink type	Identical
Latch Materials	Plastic	Plastic	Identical
Accessories	Disposable patient probe, Reusable patient probe, Heat reflecting patch, Giraffe In-Bed Scales Gravity Zone Specific, Corner trays, Giraffe monitor shelf, Swivel instrument shelf, High frequency vent porthole cover, Giraffe tubing management arm, Giraffe silo support, Patient restraint, Giraffe pressure diffusing mattress and sheet, Dovetail basket assembly, Dovetail rail extension, Ventilator mounting pole, IV pump mounting post, IV poles, Utility post, Dovetail handle, Cord wrap holders, Retaining clips, Giraffe	Disposable patient probe, Reusable patient probe, Heat reflecting patch, Giraffe In-Bed Scales Gravity Zone Specific, Corner trays, Giraffe monitor shelf, Swivel instrument shelf, High frequency vent porthole cover, Giraffe tubing management arm, Giraffe silo support, Patient restraint, Giraffe pressure diffusing mattress and sheet, Dovetail basket assembly, Dovetail rail extension, Ventilator mounting pole, IV pump mounting post, IV poles, Utility post, Dovetail handle, Cord wrap holders, Retaining clips, Giraffe	Identical

Specification	Predicate Device (K152809) Giraffe Incubator Carestation CS1	Proposed Device Giraffe Incubator Carestation CS1	Discussion of Differences
	Incubator Hood Cover, Giraffe OmniBed Hood Cover, Articulating arm for monitor/display mount, Resuscitation bag and mask holder, Cylinder Holders, Giraffe Stand-Alone Resuscitation System T-Piece or Bag & Mask, Giraffe Exam light, Giraffe Blue Spot PT Lite, BiliSoft Phototherapy Light, Giraffe Shuttle	Incubator Hood Cover, Giraffe OmniBed Hood Cover, Articulating arm for monitor/display mount, Resuscitation bag and mask holder, Cylinder Holders, Giraffe Stand-Alone Resuscitation System T-Piece or Bag & Mask, Giraffe Exam light, Giraffe Blue Spot PT Lite, BiliSoft Phototherapy Light, Giraffe Shuttle	
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

5.3 Determination of Substantial Equivalence:

Summary of Non-Clinical Testing:

The following performance data was provided in support of the substantial equivalence determination:

Compliance with Voluntary Standards

The Giraffe Incubator Carestation CS1 was designed and tested for compliance with the following standards as was the predicate Giraffe Incubator Carestation CS1 (K152809):

1. AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)

2. AAMI / ANSI / IEC 60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests

3. IEC 60601-2-19 Edition 2.1 2016-04, CONSOLIDATED VERSION Medical Electrical Equipment - Part 2-19: Particular Requirements For The Basic Safety And Essential Performance Of Infant Incubators

The Giraffe Incubator Carestation CS1 was designed and is manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485 and the following quality assurance measures were applied to the development of subject features:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance Testing (Verification)
- Safety/Reliability Testing (Verification)
- Summative Usability Testing (Validation)

Verification and Validation Testing

The proposed device has successfully completed all testing per our quality system.

Non-Clinical Testing

Evaluations of safety and effectiveness of the modified wall and porthole latches used controlled performance and reliability testing to substantiate the performance of the new latches in worst-case conditions. The specific tests and verification methods are summarized in the table below.

Table 5.1 – Functional Bench Tests Performed on Modified Latches

Test Name	Verification Method
Rough Handling Testing as per IEC60601-1 Cl 15.3.5a and IEC 60601-2-19 - Ascending Step Shock	Test
Rough Handling Testing as per IEC60601-1 Cl 15.3.5b and IEC 60601-2-19 - Descending Step Shock	Test
Rough Handling Testing as per IEC60601-1 Cl 15.3.5c and IEC 60601-2-19 - Door Frame Shock	Test
Check for Rough surfaces, sharp corners and edges (IEC 60601-1 Clause 9.3)	Test
Humidifier Operating Time	Test
Air Velocity	Test
Opening and Closing of E/W Doors and South Wall	Test
Opening of Doors and Portholes	Test
E/W Doors latch mechanism and N/S Walls as Barriers (IEC 60601-2-19 Clause 201.9.8.3.101)	Test
Porthole latch mechanism as Barriers (IEC 60601-2-19 Clause 201.9.8.3.101)	Test
Removing of E/W Doors and infant compartment design	Test
Maximum sidewall upright angle	Test
Porthole Latch: Over Torque Test	Reliability Test
Wall Latch and Porthole Latch: Vibration / Reliability Threshold Test	Reliability Test
Porthole Latch: Push Load	Reliability Test
Porthole Latch: Pull Load for Cleaning	Reliability Test
Porthole Latch: Open Close Cycles of Knob Latch	Reliability Test
Porthole Latch: Cleaning Pull Cycles of Knob Latch	Reliability Test
Wall Latch: Handling Load Test	Reliability Test
Wall Latch: Pull and Push Loads with chemical exposure	Reliability Test
Wall Latch: Handling Load on Snap	Reliability Test
Wall Latch: Pinch Action Open Close Cycles	Reliability Test
Wall Latch: Push Close Cycles (Push to Close from Secondary Latch Position to Primary Latch Position)	Reliability Test

Animal Study

The Giraffe Incubator Carestation CS1 did not require animal tests to support substantial equivalence.

Clinical Studies

The Giraffe Incubator Carestation CS1 did not require clinical tests to support substantial equivalence.

Human Factors Analysis

The Giraffe Incubator Carestation CS1 successfully completed a summative usability study of the modified wall and porthole latches and their instructions for use. There were no findings from the summative usability testing that led to changes in wall latches, porthole latches, or on-product labeling. The latch modifications did not introduce any new risks or use-related issues.

Conclusion:

The modifications associated with Giraffe Incubator Carestation CS1 do not change the Indications for Use or intended use from the predicate, and represent equivalent technological characteristics, with no impact on energy type, operating principles, or primary control mechanisms.

Design verification, along with bench testing demonstrate the proposed incubator system is substantially equivalent and as safe and as effective as the legally marketed predicate device. Clinical data was not required to demonstrate substantial equivalence. GE Healthcare's quality system's design, verification, validation, and risk management processes did not identify any new hazards, unexpected results, or adverse effects stemming from the changes to the predicate. The modified system continues to meet all applicable IEC 60601-1 series of standards.

Based on development under GE Healthcare's quality system, the successful verification, engineering bench testing, and usability testing, GE Healthcare believes that the Giraffe Incubator Carestation CS is substantially equivalent to the predicate device (K152809). The summary above demonstrates that there are no new questions of safety or effectiveness for the Giraffe Incubator Carestation.