July 28, 2026

Datex-Ohmeda, Inc.
Isabel McGann
Director, Regulatory Affairs, Maternal Infant Care
3114 N Grandview Blvd.
Waukesha, Wisconsin 53188

Re: K260326
Trade/Device Name: Giraffe™ OmniBed™ Carestation (CS1); Giraffe™ Incubator Carestation (CS1)
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal incubator
Regulatory Class: Class II
Product Code: FMZ, FMT
Dated: June 30, 2026
Received: June 30, 2026

Dear Isabel McGann:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

DAVID WOLLOSCHECK -S

David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260326

Device Name
Giraffe™ OmniBed™ Carestation (CS1);
Giraffe™ Incubator 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%).

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.

510(k) Summary – K260326

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

Date:	23 July 2026
Owner/Submitter:	GE HealthCare (dba Datex- Ohmeda, Inc.) 3114 N. Grandview Blvd Waukesha, WI 53188
Primary Contact Person:	Isabel McGann Regulatory Affairs Director GE HealthCare Phone: (720) 447-0747 Email: Isabel.mcgann@gehealthcare.com
Secondary Contact Person:	Jordan Baum Regulatory Affairs Program Manager GE HealthCare Phone: (574) 529-1811 Email: Jordan.baum@gehealthcare.com
Device Trade Name(s):	Giraffe™ OmniBed™ Carestation (CS1) Giraffe™ Incubator Carestation (CS1)
Common/Usual Name:	Giraffe OmniBed Carestation (CS1): Neonatal Incubator/Infant Radiant Warmer Giraffe Incubator Carestation (CS1): Neonatal Incubator
Regulation:	Neonatal Incubator
Classification:	21 CFR 880.5400
Product Code:	FMZ, FMT
Predicate Device:	Giraffe Omnibed Carestation (CS1). K251663 Giraffe Incubator Carestation (CS1), K251663
Device Description:	The **Giraffe OmniBed Carestation (CS1)** is a device that can function as an incubator (in the closed mode) or as an infant radiant warmer (in the open mode) based on the user's selection. Incubators and warmers provide heat in a controlled manner to neonates who are unable to thermoregulate based on their own physiology. In the closed bed mode of operation, the bed functions as an incubator, maintaining the infant's temperature by circulating heated air within the enclosed bed compartment. Warm air is circulated through the closed patient 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. In the open bed mode, 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. Accessories for the Giraffe OmniBed include an optional weighing scale, optional Servo Oxygen, Uninterruptible Power Supply (UPS), Giraffe Shuttle, Mounting Accessories Rail,

	Shelves, and Patient Probes.
	The **Giraffe Incubator Carestation (CS1)** 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. Accessories for the Giraffe Incubator include an optional weighing scale, optional Servo Oxygen, Uninterruptible Power Supply (UPS), Giraffe Shuttle, Mounting Accessories Rail, Shelves and Patient Probes.
Indications 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%).
	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%).

A comparison of the indications for use and technological features of the subject and predicate device is provided in Table 1 below.

Table 1: High-level Comparison of Subject Device, Giraffe Omnibed CareStation (CS1), to Predicate

Specification:	**Predicate Device:** Giraffe Omnibed Carestation CS1 (K251663)	**Subject Device:** Giraffe Omnibed Carestation CS1	**Discussion of Differences:**
Indications 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%).	**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%).	Identical

Specification:	**Predicate Device:** Giraffe Omnibed Carestation CS1 (K251663)	**Subject Device:** Giraffe Omnibed Carestation CS1	**Discussion of Differences:**
Product Code	FMZ, FMT	FMZ, FMT	Identical
Contraindications	None	None	Identical
User Population	Professional Use Only	Professional Use Only	Identical
Environment of Use	Labor and Delivery, NICU, or Newborn Nursery	Labor and Delivery, NICU, or Newborn Nursery	Identical
Fundamental Principle of Operation	Enclosed infant bed for thermal support. The device maintains the infant's temperature by circulating heated air within the closed bed compartment. Controller-based, open care radiant warmer that facilitates thermoregulation and emergency resuscitation of infants.	Enclosed infant bed for thermal support. The device maintains the infant's temperature by circulating heated air within the closed bed compartment. Controller-based, open care radiant warmer that facilitates thermoregulation and emergency resuscitation of infants.	Identical
Sterility	Non-sterile device	Non-sterile device	Identical
Alarm Silence	Two Options: • Touch Screen Silence • Hands free Alarms Silence (HFAS)	Two Options: • Touch Screen Silence • Hands free Alarms Silence (HFAS)	Identical
Dimensions	Weight: 149 kg Height: 152 cm (bed lowered)/ 178 cm (bed raised) Width: 68 cm Depth: 114 cm	Weight: 149 kg Height: 152 cm (bed lowered)/ 178 cm (bed raised) Width: 68 cm Depth: 114 cm	Identical
Bed Tilt	Mattress tilt angle: 12°	Mattress tilt angle: 12°	Identical
Electrical Power Ratings	11.5@ 100V ~ 50/60 Hz 9.5A @115V ~ 50/60 Hz 5.5A @ 220/230/240V ~ 50/50 Hz	11.5@ 100V ~ 50/60 Hz 9.5A @115V ~ 50/60 Hz 5.5A @ 220/230/240V ~ 50/50 Hz	Identical
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
User Control Settings	• Patient control temperature 35-37.5°C in 0.1° increments	• Patient control temperature 35-37.5°C in 0.1° increments	Identical

Specification:	**Predicate Device:** Giraffe Omnibed Carestation CS1 (K251663)	**Subject Device:** Giraffe Omnibed Carestation CS1	**Discussion of Differences:**
	• Air control temperature 20-39°C in 0.1 increments • Radiant heat power 0-100% in 5% increments • Humidity 30- 95 % RH in 5% increments	• Air control temperature 20-39°C in 0.1 increments • Radiant heat power 0-100% in 5% increments • Humidity 30- 95 % RH in 5% increments	
Materials	Use of polyacetal components in some assemblies	Contains polyester components in some assemblies with equivalent performance and specifications	Different Material changes were adequately evaluated in consideration of the requirements of ISO 18562 and ISO 10993. All testing passed.
Software Cybersecurity	Meets current cybersecurity expectations	Meets current cybersecurity expectations	Identical

Table 2: High-level Comparison of Subject Device, Giraffe Incubator CareStation (CS1), to Predicate

Specification	**Predicate Device:** Giraffe Incubator Carestation CS1 (K251663)	**Subject Devices:** 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	**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	Identical

Specification	**Predicate Device:** Giraffe Incubator Carestation CS1 (K251663)	**Subject Devices:** Giraffe Incubator Carestation CS1	**Discussion of Differences**
	value set by the operator (21-65%).	value set by the operator (21-65%).	
Product Code	FMZ	FMZ	Identical
Contraindications	None	None	Identical
User Population	Professional Use Only	Professional Use Only	Identical
Environment of Use	Labor and Delivery, NICU, or Newborn Nursery	Labor and Delivery, NICU, or Newborn Nursery	Identical
Fundamental Principle of Operation	Enclosed infant bed for thermal support. The device maintains the infant's temperature by circulating heated air within the closed bed compartment.	Enclosed infant bed for thermal support. The device maintains the infant's temperature by circulating heated air within the closed bed compartment.	Identical
Sterility	Non-sterile device	Non-sterile device	Identical
Alarm Silence	Two Options: • Touch Screen Silence • Hands free Alarms Silence (HFAS)	Two Options: • Touch Screen Silence • Hands free Alarms Silence (HFAS)	Identical
Dimensions	Weight: 138 kg Height: 152 cm (bed lowered)/ 178 cm (bed raised) Width: 66 cm Depth: 114 cm	Weight: 138 kg Height: 152 cm (bed lowered)/ 178 cm (bed raised) Width: 66 cm Depth: 114 cm	Identical
Bed Tilt	Mattress tilt angle: 12°	Mattress tilt angle: 12°	Identical
Electrical Power Ratings	11.5@ 100V ~ 50/60 Hz 9.5A @115V ~ 50/60 Hz 5.5A @ 220/230/240V ~ 50/50 Hz	11.5@ 100V ~ 50/60 Hz 9.5A @115V ~ 50/60 Hz 5.5A @ 220/230/240V ~ 50/50 Hz	Identical
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
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 30- 95 % RH 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 30- 95 % RH in 5% increments	Identical

Specification	**Predicate Device:** Giraffe Incubator Carestation CS1 (K251663)	**Subject Devices:** Giraffe Incubator Carestation CS1	**Discussion of Differences**
Materials	Use of polyacetal components in some assemblies	Contains polyester components in some assemblies with equivalent performance and specifications	Different Material changes were adequately evaluated in consideration of the requirements of ISO 18562 and ISO 10993. All testing passed.
Software Cybersecurity	Meets current cybersecurity expectations	Meets current cybersecurity expectations	Identical

PERFORMANCE DATA: Determination of Substantial Equivalence

Summary of Non-Clinical Tests:

The safety and effectiveness of the replacement materials used at different locations in the breathing gas pathway was evaluated per ISO 18562, and the results met the acceptance criteria without any deviations. In addition, bench verification testing included Device/System Functional Verification Testing, Non-Operating and Device Packaging Testing, Verification by Analysis, Material Stress Testing, and Reliability Testing. All verification results were determined to be PASS, with any deviations assessed and determined not to impact testing results. No additional non-clinical testing beyond the testing described above was required in support of the material changes.

Compliance with Voluntary Standards:

The following FDA recognized consensus standards were used to demonstrate substantial equivalence:

- ANSI AAMI ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds

- ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes
- ANSI AAMI ISO 14971: 2019 Medical devices - Applications of risk management to medical devices
- ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
- IEC 60601-2-19: 2020 (3rd ed) Medical electrical equipment –Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators
- IEC 60601-2-21:2020 (3rd ed) Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
- ISTA 3B 2017 - Packaged-Products for Less-Than-Truckload (LTL) Shipment
- ISO 17664-1:2021, Processing of health care products Information to be provided by the medical device manufacturer for the processing of medical devices
- ISO 17664-2: 2021, Processing of health care products Information to be provided by the medical device manufacturer for the processing of medical devices

Biocompatibility

Evaluations of safety and effectiveness of the device with new plastic materials was performed to substantiate the performance of the updated device in accordance with ISO 10993 and ISO 18562. All results passed.

Reprocessing

Note that the material changes have not affected the cleaning or disinfection instructions or validated state of the device. The changes are in material selection only and do not affect the features, geometry, or surface texture of the impacted components. However, changes to material require additional evaluation of chemical compatibility for the chemicals listed in the product labeling. Chemical compatibility evaluation demonstrates that the stability of the device over the duration of the expected service life is not affected by the changes in materials.

Human Factors

The material changes do not impact the usability of the devices therefore no new human factors testing was completed to support substantial equivalence.

Software and Cybersecurity

The material changes have no impact on software. However, in accordance with Section 524B of the Food Drug and Cosmetic Act (FD&C Act) and “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff, Document issued on June 27, 2025, current cybersecurity content has been included.

CONCLUSION:

The results of the testing described above demonstrate that the Giraffe Incubator Carestation CS1 and Giraffe OmniBed Carestation CS1 are as safe and effective as the predicate devices and support a determination of substantial equivalence.