October 22, 2025

Datex-Ohmeda. Inc.
Jordan Baum
Regulatory Affairs Program Manager
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K251663
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: September 22, 2025
Received: September 22, 2025

Dear Jordan Baum:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Colleen J. Lawrimore -S

Colleen Lawrimore, Ph.D.
For 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)*
K251663

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 - K251663:

Date:	21 October 2025
Owner/Submitter:	Datex-Ohmeda, Inc. 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Jordan Baum Regulatory Affairs Program Manager GE HealthCare Phone: (574) 529-1811 Email: jordan.baum@gehealthcare.com
Secondary Contact Person:	Shiwani Zalpuri Regulatory Affairs Program Manager GE HealthCare Phone: +91-9871090801 Email: shiwani.zalpuri@gehealthcare.com
Device Trade Names:	Giraffe OmniBed Carestation (CS1); Giraffe Incubator Carestation (CS1)
Common/Usual Name:	Giraffe OmniBed Carestation (CS1): Incubator/Warmer Giraffe Incubator Carestation (CS1): Incubator
Regulation Names:	Neonatal Incubator
Regulation Number:	21 CFR 880.5400
Classification:	Class II
Product Codes:	FMZ, FMT
Predicate Devices:	K213551 - Giraffe OmniBed Carestation (CS1) K213553 - Giraffe Incubator Carestation (CS1)
Predicate Device Manufacturer:	Datex-Ohmeda, Inc. 9900 Innovation Drive Wauwatosa, WI 53226, USA
Device Description:	**The Giraffe OmniBed Carestation** 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 thermo-regulate 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. The Giraffe OmniBed Carestation incorporates an optional weighing scale, Servo O2, Uninterruptible Power Supply (UPS) & Shuttle, Mounting Accessories Rail and Shelves and Storage drawers. **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.

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE:

A comparison of the indications for use and technological features of the subject and predicate devices are provided in Table 1 and Table 2, below.

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

Specification:	**Predicate Device:** Giraffe Omnibed Carestation CS1 (K213551)	**Subject Device**: Giraffe Omnibed Carestation CS1 (K251663)	**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
Product code	FMZ, FMT	FMZ, FMT	Identical

Specification:	**Predicate Device:** Giraffe Omnibed Carestation CS1 (K213551)	**Subject Device**: Giraffe Omnibed Carestation CS1 (K251663)	**Discussion of Differences:**
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 Mattress Size: 48.8 cm x 64.8 cm Height: 152 cm (bed lowered)/ 178 cm (bed raised) Width: 68 cm Depth: 114 cm	Weight: 149 kg Mattress Size: 48.8 cm x 64.8 cm 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 (K213551)	**Subject Device**: Giraffe Omnibed Carestation CS1 (K251663)	**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	
Mattress Cover	Polyurethane Laminated Fabric – Dartex P091	Polyurethane Laminated Fabric - Dartex PER200	Different Same material type (polyurethane laminated fabric). Material changes were evaluated per the requirements of ISO 10993 to demonstrate substantial equivalence. All testing passed.
Mattress inner Foam material	Polyurethane foam (NCFI, UC-17) Polyurethane foam (NCFI, AVE-2610 or AVE-3010)	Polyurethane foam (FXI Foam, No .1.85 AESUL) Polyurethane foam (NCFI, VX-3010)	Different Same material type (polyurethane). Material changes were evaluated per the requirements of ISO 18562 to demonstrate substantial equivalence. All testing passed.
Software - Cybersecurity	Met current cybersecurity expectations	Revisions to device software for improvements to device cybersecurity, to meet requirements of section 524B of the FD&C act.	Different Software updates are improvements to the cybersecurity of the device, to add additional protections and mitigations for security risk identified

Specification:	**Predicate Device:** Giraffe Omnibed Carestation CS1 (K213551)	**Subject Device**: Giraffe Omnibed Carestation CS1 (K251663)	**Discussion of Differences:**
			as part of continuous cybersecurity management activities. No changes to the clinical functions of the device software. Updated software has been fully verified.

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

Specification	**Predicate Device:** Giraffe Incubator Carestation CS1 (K213553)	**Subject Devices:** Giraffe Incubator Carestation CS1 (K251663)	**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
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	Enclosed infant bed for thermal support. The device maintains the infant's	Identical

Specification	**Predicate Device:** Giraffe Incubator Carestation CS1 (K213553)	**Subject Devices:** Giraffe Incubator Carestation CS1 (K251663)	**Discussion of Differences**
	heated air within the closed bed compartment.	temperature by circulating heated air within the closed bed compartment.	
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 Mattress Size: 48.8 cm x 64.8 cm Height: 152 cm (bed lowered)/ 178 cm (bed raised) Width: 66 cm Depth: 114 cm	Weight: 138 kg Mattress Size: 48.8 cm x 64.8 cm 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
Mattress Cover	Polyurethane Laminated Fabric – Dartex P091	Polyurethane Laminated Fabric - Dartex PER200	Different Same material type (polyurethane laminated fabric). Material changes were evaluated per the requirements of ISO 10993 to demonstrate substantial

Specification	**Predicate Device:** Giraffe Incubator Carestation CS1 (K213553)	**Subject Devices:** Giraffe Incubator Carestation CS1 (K251663)	**Discussion of Differences**
			equivalence. All testing passed.
Mattress inner Foam material	Polyurethane foam (NCFI, UC-17) Polyurethane foam (NCFI, AVE-2610 or AVE-3010)	Polyurethane foam (FXI Foam, No .1.85 AESUL) Polyurethane foam (NCFI, VX-3010)	Different Same material type (polyurethane). Material changes were evaluated per the requirements of ISO 18562 to demonstrate substantial equivalence. All testing passed.
Software - Cybersecurity	Met current cybersecurity expectations	Revisions to device software for improvements to device cybersecurity, to meet requirements of section 524B of the FD&C act.	Different Software updates are improvements to the cybersecurity of the device, to add additional protections and mitigations for security risk identified as part of continuous cybersecurity management activities. No changes to the clinical functions of the device software. Updated software has been fully verified.

PERFORMANCE DATA: Determination of Substantial Equivalence

Summary of Non-Clinical Tests:

In order to evaluate the updated foam material, performance testing was conducted on the updated mattress foam. The mattress was analyzed for multiple functional aspects, namely Peak Pressure test, X-Ray test, Adhesive Strength test, and Humidity Degradation assessment. All functional aspects of the test acceptance criteria in the verification plans have been met without any deviations.

No additional non-clinical testing was performed in support of the mattress material changes.

Compliance with Voluntary Standards:

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

1. ANSI AAMI ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
2. ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
3. ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
4. ISO 10993-18 Second edition 2020-01 Amendment 1 2022-05 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
5. ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation
6. ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
7. ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
8. ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
9. ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes
10. ANSI AAMI ISO 14971: 2019 Medical devices - Applications of risk management to medical devices

Biocompatibility

Evaluations of safety and effectiveness of the updated mattress was performed to substantiate the biocompatibility of the updated Mattress in accordance with ISO 10993 and ISO 18562. All results passed.

Reprocessing

There is no impact of the change on the reprocessing, sterilization, & shelf life of the predicate devices

hence Giraffe Incubator Carestation CS1 and Giraffe OmniBed Carestation CS1 therefore no new reprocessing data is included.

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), current Cybersecurity content has been included in alignment with the FDA Guidance, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions dated September 2023. This includes information on changes to device software for continuous improvements to cybersecurity.

Software and cybersecurity verification activities were conducted on the device to confirm effective implementation of the software updates and demonstrate adequate cybersecurity.

Summary of Clinical testing
No clinical data is included in support of substantial equivalence. The material changes did not impact the need to perform clinical tests to support substantial equivalence.

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 supports a determination of substantial equivalence.