February 12, 2021

GE Healthcare
Michelle Johnson
Sr. Regulatory Affairs Leader
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K201628
Trade/Device Name: Panda iRes Warmer, Giraffe Warmer
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: Class II
Product Code: FMT
Dated: December 21, 2020
Received: December 22, 2020

Dear Michelle Johnson:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201628

Device Name Panda iRes Warmer , Giraffe Warmer

Indications for Use *(Describe)*
Infant radiant warmers provide infrared heat in a controlled manner to neonates who are unable to thermoregulate based on their own physiology. Infant radiant warmers may be used to facilitate the neonate's transition to the external environment or to provide a controlled open environment. An optional integrated SpO2 monitoring feature may be used for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (Sp02) and pulse rate (measured by a SpO2 sensor). An optional integrated resuscitation system may be used to provide the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the infant.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K201628 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:	
Date:	February 12, 2021
Primary Contact Person:	Michelle Johnson Sr. Regulatory Affairs Leader Datex-Ohmeda, Inc. 9900 Innovation Drive Wauwatosa, WI 53226 Phone: 414-429-9263 Email: Michelle.Johnson@ge.com
Secondary Contact Person:	Lee Bush Regulatory Affairs Director Datex-Ohmeda, Inc. Phone: 262-309-9429 Email: Lee.Bush@ge.com
Device Trade Name:	Panda iRes Warmer, Giraffe Warmer
Common/Usual Name:	Infant Warmer
Classification Names:	Warmer, Infant Radiant
Regulation	21 CFR 880.5130 Infant radiant warmer.
Classification	II
Product Code:	FMT
Predicate Device:	Panda Warmer, Giraffe Warmer (K122267)

Indications for Use:	Infant radiant warmers provide infrared heat in a controlled manner to neonates who are unable to thermoregulate based on their own physiology. Infant radiant warmers may be used to facilitate the neonate's transition to the external environment or to provide a controlled open environment. An optional integrated SpO2 monitoring feature may be used for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (Sp02) and pulse rate (measured by a SpO2 sensor). An optional integrated resuscitation system may be used to provide the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the infant.
Comparison of Intended Use	There is no change to the intended use of the Panda iRes Warmer or Giraffe Warmer.

5.1 Device Description:

The Panda iRes Warmer and Giraffe Warmer are infant radiant warmers with a heating source intended to maintain the thermal balance of an infant patient by direct radiation of energy in the infrared region of the electromagnetic spectrum. This device also provides optional integrated SpO_2 Monitoring and Resuscitation.

Radiant heat from an infrared heat source is focused onto the bed to warm the patient. The operator may select either the heater power or skin temperature control method. Depending on the control method selected, the heater is either regulated at the operator selected power level or the heater output is modulated to maintain the patient's temperature at the value selected by the operator.

The subject devices have two control modes, Manual Mode and Baby Mode. In the manual Mode, the warmer controls radiant heater output from a heater power percentage setting that you enter using the control panel. In baby mode, the warmer controls radiant heater output based on temperature readings from a probe attached to the baby's skin (skin temperature probe and the reflective probe patch) and a set temperature (set temp) you enter using the control panel.

5.2 Comparison of Technological Characteristics with the Predicate Device

The modified Panda iRes Warmer and Giraffe Warmer are infant radiant warmers

developed on the same platform as predicate Panada iRes Warmer and Giraffe Warmer (K122267). The proposed modifications to the Panda iRes Warmer and Giraffe Warmer include changes to strengthen the bedside panels and latches (including changing the material of the bedside panel latch from plastic to metal), to better withstand forces in the event of misuse by maneuvering the warmer by pulling the bedside panel wall. The bedside panel design is modified to accommodate the changed latch. These modifications to the bedside panel are mechanical in nature.

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 Panda iRes Warmer and Giraffe Warmer is designed and tested for compliance with the following performance standards:

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 60601-2-21 Edition 2.1 2016-04, CONSOLIDATED VERSION Medical Electrical Equipment - Part 2-21: Particular Requirements For The Basic Safety And Essential Performance Of Infant Radiant Warmers [Including: Amendment 1 (2016)]

The Panda iRes and Giraffe Warmer 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 bedside panel used controlled engineering test fixtures to substantiate the performance of the new panel to worst-case conditions. Various mathematical and statistical analyses were performed to demonstrate that each performance item was successfully verified. The type of test and method of verification are listed in the table below.

Test Name	Verification Method
South Door Pull Test (includes Wall 20N IEC Push Test)	Test
South Wall 660N Static Load Verification	Test
Impact Test – Door shock frame test per IEC 60601-1 – 15.3.5.c.	Test
Wall Threshold Test – Modified threshold test per IEC 60601-1 – 9.4.2.4.3 with operator pulling on wall instead of pushing on handle	Test
East and West side panels are interchangeable	Analysis
Wall Ergonomics – Caregiver Proximity	Analysis
Panel Corner Spacing	Analysis
Drawer Access	Analysis
Side Wall Removal	Analysis
Walls are Cleanable	3rd Party Test
Reliability - Wall Latch / Bed Pin Wear Test	Test
Reliability - Wall Pull Fatigue Test	Test
Reliability - Wall Lean Push Fatigue – Wall in Up Position	Analysis
Reliability - Wall Knee Push Fatigue – Wall in Down Position	Test

Animal Study
The Panda iRes Warmer and Giraffe Warmer did not require animal tests to support substantial equivalence.

Clinical Studies
The Panda iRes Warmer and Giraffe Warmer did not require clinical tests to support substantial equivalence.

Reprocessing
The device modifications have been validated for processing in accordance with recommended evaluations as listed in *AAMI TIR12* and *Guidance for Industry and FDA Staff –*

Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.

Human Factors Analysis

The modifications to the Panda iRes Warmer and Giraffe Warmer required summative usability for the bedside panel instructions for use.

Conclusion:

GE Healthcare considers the modified Panda iRes Warner and Giraffe Warmer to be as safe, as effective, and the performance to be substantially equivalent to the predicate device. Non-clinical tests have been summarized in the verification and validation testing. The testing was completed with passing results per the acceptance criteria defined in the test cases. Based on development under GE Healthcare's quality system, the successful verification and engineering bench testing, GE Healthcare believes that the Panda iRes Warmer and Giraffe Warmer perform in a substantially equivalent manner to the predicate devices (K122267) and hence is safe and effective for its intended use.