January 17, 2025

Draeger Medical Systems, Inc.
Karl Nittinger
Senior Manager, Regulatory Affairs
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K243606
Trade/Device Name: Babyroo TN300
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: Class II
Product Code: FMT
Dated: November 21, 2024
Received: November 21, 2024

Dear Karl Nittinger:

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,

Porsche Bennett

Porsche Bennett
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)*
K243606

Device Name
Babyroo TN300

Indications for Use *(Describe)*
The Babyroo TN300 is an open care radiant warmer that provides a controlled source of heat and regulation of skin temperature for neonates and infants. The optional integrated resuscitation module provides emergency respiratory support administered by clinicians and includes the functionality of suction. Additionally, the device provides weighing (optional) and pulse oximetry (optional) of neonates and infants. The device is designed for use with patients with a body weight up to 10 kg (22 lb).

The device is indicated for thermoregulation, skin temperature regulation, weighing (optional), pulse oximetry (optional), and resuscitation (optional) of neonates and infants.

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

K243606

1. **Submitter**:

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford, PA 18969

Contact Person:

Karl Nittinger
Senior Manager, Regulatory Affairs
E-Mail: karl.nittinger@draeger.com
Telephone: 267-272-1913

Date prepared: 17 January 2025

2. **Device**:

Trade Name:	Babyroo TN300
Classification Name:	Warmer, Infant Radiant
Regulation Number:	21 CFR §880.5130
Product Code:	FMT
Class:	II

3. Predicate Devices

The purpose of this premarket notification is the modification of the subject Babyroo TN300 infant warmer device, which was originally cleared under K230278. The modification consists of the activation, for the US market, of existing optional software functionality to facilitate the subject Babyroo TN300 device's display of SpO_2 information that is generated by existing, cleared, pulse oximetry accessories.

The predicate device that is utilized in this premarket notification to support substantial equivalence is:

Primary Predicate Device	510(k)	Manufacturer
Babyroo TN300	K230278	Draeger Medical Systems, Inc.

4. Device Description

The purpose of this premarket notification is to activate, for the US market, existing optional functionality which enables the display of SpO_2 information by the subject Babyroo TN300 via its graphical user interface (GUI). The SpO_2 display functionality is facilitated through connection with existing, cleared pulse oximetry accessories which generate the SpO_2 information that is displayed on the subject Babyroo TN300 GUI.

The existing, cleared pulse oximetry technology accessories identified for use with the subject Babyroo TN300 device to facilitate its display of SpO_2 information are:

- Draeger Infinity MCable® Masimo SET®: Provides connection interface between the subject Babyroo TN300 and OEM Masimo SpO_2 sensors. Contains the cleared OEM Masimo SET® pulse oximetry technology.
- Masimo RD SET OEM neonatal SpO_2 sensors
- Masimo LNCS Y-I OEM neonatal SpO_2 sensors
- Masimo LNCS OEM neonatal SpO_2 sensors

As subject to the modification in this premarket notification, in addition to the display of SpO_2 information by the Babyroo TN300, the clinician user can also set SpO_2 alarm limits via the subject device's GUI.

There are no other modifications under the scope of this premarket notification to the subject Babyroo TN300 device compared to its original clearance under K230278.

As originally cleared under K230278:

The Babyroo TN300 is an open care infant radiant warmer that provides controlled source heat and skin temperature display for use with neonates and infants. The device can be configured for either labor and delivery or the newborn intensive care unit (NICU) and can be used for intra hospital transfer. Warming therapy is interrupted during intra hospital transfer and patient is not supplied with heat.

The Babyroo TN300 device is offered with a fixed height or adjustable height trolley configuration and provides two heat sources for infant warming: a radiant warmer and an optional heating plate with conductive gel mattress. The device's bed can be tilted up to 15° in Trendelenburg and reverse Trendelenburg directions and the design of the device is intended to facilitate uniform heat distribution over the entire mattress surface across the range of bed tilt angulation. An optional removable canopy is available for intra-hospital transfer.

Infant warming is facilitated via three (3) available thermoregulation modes:

- Manual mode
- Skin temperature mode
- Kangaroo mode

In manual mode, the warmer power is set manually by the clinician. Supply of heat from the radiant warmer at power settings above 30% are limited by the device to predefined time intervals.

In skin temperature mode, the temperature is regulated by means of a temperature setting determined by the clinician and skin temperature sensors applied to the infant patient.

In kangaroo mode, warming is provided by the infant's parent's body heat. The infant's temperature must be monitored continuously during kangaroo mode.

The Babyroo TN300 is available with an optional Resuscitation module. The optional Resuscitation module is pneumatically powered, can be connected to central gas supplies or gas cylinders, and provides emergency resuscitation and suction to the patient. The optional Resuscitation module includes adjustment for gas flow, peak inspiratory pressure, O_2 concentration, and suction functionality and is available in three (3) variants:

- Resuscitation module with gas mixer and AutoBreath®.
- Resuscitation module with gas mixer.
- Resuscitation with O_2 only.

The optional AutoBreath® function facilitates pneumatically driven, automatic respiratory rate and positive end-expiratory pressure control.

The Babyroo TN300 can be configured to include an optional integrated electronic scale, as well as, optional heated gel mattress, optional integrated single or dual storage drawers, optional gas cylinder holders, and optional x-ray tray.

The Babyroo TN300 device has an expected service life of 10 years. The expected service life is an attribute related to the conformity requirements of international standard: IEC 60601-1 and is defined as the time period during which the device is expected to remain suitable for its intended use and in which all risk control measures need to remain effective. Maintenance, inspection, and service intervals required to ensure the proper functioning of the device within its expected service life are defined in the instructions for use.

5. Indications for Use

The Babyroo TN300 is an open care radiant warmer that provides a controlled source of heat and regulation of skin temperature for neonates and infants. The optional integrated resuscitation module provides emergency respiratory support administered by clinicians and includes the functionality of suction. Additionally, the device provides weighing (optional) and pulse oximetry (optional) of neonates and infants. The device is designed for use with patients with a body weight up to 10 kg (22 lb).

The device is indicated for thermoregulation, skin temperature regulation, weighing (optional), pulse oximetry (optional), and resuscitation (optional) of neonates and infants.

6. Substantial Equivalence Comparison and Discussion

	Subject Device	Predicate Device	Comment
	Babyroo TN300 (K243606)	**Babyroo TN300 (K230278)**	
Regulation	880.5130	880.5130	**Same –** The subject, device and the predicate device (K230278) are Class II devices regulated under 880.5130 (product code: FMT).
Product Code	FMT	FMT	
Classification	Class II	Class II	
Indications for Use	The Babyroo TN300 is an open care radiant warmer that provides a controlled source of heat and regulation of skin temperature for neonates and infants. The optional integrated resuscitation module provides emergency respiratory support administered by clinicians and includes the functionality of suction. Additionally, the device provides weighing (optional) **and pulse oximetry (optional)** of neonates and infants. The device is designed for use with patients with a body weight up to 10 kg (22 lb). The device is indicated for thermoregulation, skin temperature regulation, weighing (optional), **pulse oximetry (optional),** and resuscitation (optional) of neonates and infants.	The Babyroo TN300 is an open care radiant warmer that provides a controlled source of heat and regulation of skin temperature for neonates and infants. The optional integrated resuscitation module provides emergency respiratory support administered by clinicians and includes the functionality of suction. Additionally, the device provides weighing (optional) of neonates and infants. The device is designed for use with patients with a body weight up to 10 kg (22 lb). The device is indicated for thermoregulation, skin temperature regulation, weighing (optional), and resuscitation (optional) of neonates and infants.	**Different –** The subject, device and the predicate device (K230278) are both primarily intended for use for the thermoregulation of infant and neonate patients with the inclusion of optional resuscitation and weighing. The weight limitation (10 kg) for the subject, device is identical to the predicate device (K230278) and is established in the contraindications of both devices. The only difference in the indications for use of the subject, device and the predicate device (K230278) is the addition of optional pulse oximetry in the proposed indications for use of the subject device.
Contraindications	The device is contraindicated for patients with a body weight above 10 kg (22 lb).The device is not intended for use outside of the specified environments of use.	The device is contraindicated for patients with a body weight above 10 kg (22 lb).The device is not intended for use outside of the specified environments of use.	**Same –** The subject device and the predicate device are both contraindicated for patients with a body weight above 10 kg (22 lb) and for use outside of the specified environments of use.

	Subject Device Babyroo TN300 (K243606)	Predicate Device Babyroo TN300 (K230278)	Comment
System Specifications			
Environment of Use	Intended for use in the following environments: – Labor and delivery units – Pediatric intensive care units – Neonatal intensive care units – Operating rooms – During intrahospital patient transfer	Intended for use in the following environments: – Labor and delivery units – Pediatric intensive care units – Neonatal intensive care units – Operating rooms – During intrahospital patient transfer	**Same –** The intended environments of use for the subject device and the predicate device (K230278) are identical.
Fundamental principle of operation	Controller-based, open care radiant warmer that facilitates thermoregulation and emergency resuscitation of infants.	Controller-based, open care radiant warmer that facilitates thermoregulation and emergency resuscitation of infants.	**Same –** The fundamental principle of operation of the subject device is the identical to that of the predicate device (K230278).
Radiant Warmer			
Irradiance	30% power – 10 mW/cm^2 60% power – 18 mW/cm^2 100% power – 32 mW/cm^2	30% power – 10 mW/cm^2 60% power – 18 mW/cm^2 100% power – 32 mW/cm^2	**Same –** The subject Babyroo TN300 device features the same irradiance performance and specifications as the predicate Babyroo TN300 device (K230278).
Pre-warm Procedure	Power Duration Display 1. 100% 3 min. "Pre" 2. 60% 11.5 min. "Pre" 3. 30% * "30" *Until clinician sets a value.	Power Duration Display 1. 100% 3 min. "Pre" 2. 60% 11.5 min. "Pre" 3. 30% * "30" *Until clinician sets a value.	**Same –** The subject Babyroo TN300 device incorporates the same power sequence during pre-warm as the predicate Babyroo TN300 device (K230278).
Warming Therapy Modes	- Skin temperature mode - Manual mode - Kangaroo mode	- Skin temperature mode - Manual mode - Kangaroo mode	**Same –** The warming therapy modes offered by the subject Babyroo TN300 device are in the same as the warming therapy modes offered by the predicate Babyroo TN300 device (K230278).
Skin Temperature Mode	Temperature control by set value for the skin temperature. The temperature can be set in steps of 0.1 °C (0.1 °F). Temperature Range Settings: 34°C to 37°C (93.2°F to 98.6°F) Extended range: 37.1°C to 38°C (98.7°F to 100.4°F)	Temperature control by set value for the skin temperature. The temperature can be set in steps of 0.1 °C (0.1 °F). Temperature Range Settings: 34°C to 37°C (93.2°F to 98.6°F) Extended range: 37.1°C to 38°C (98.7°F to 100.4°F)	**Same –** The skin temperature mode in the subject Babyroo TN300 device is identical to that of the predicate Babyroo TN300 device (K230278).

	Subject Device	Predicate Device	Comment
	Babyroo TN300 (K243606)	**Babyroo TN300 (K230278)**	
System Specifications			
Radiant Warmer (continued)			
Manual warming mode	Radiant warmer power is set manually. If the user sets the radiant warmer power above 30 %, a timer starts and the following alarms are displayed after predefined time intervals: – After 14 minutes the "***Check patient's condition***" alarm is displayed. – After 15 minutes, the radiant warmer is switched off and the "***Warmer off, check patient's condition alarm***" is displayed.	Radiant warmer power is set manually. If the user sets the radiant warmer power above 30 %, a timer starts and the following alarms are displayed after predefined time intervals: – After 14 minutes the "***Check patient's condition***" alarm is displayed. – After 15 minutes, the radiant warmer is switched off and the "***Warmer off, check patient's condition alarm***" is displayed.	**Same –** The manual warming mode in the subject Babyroo TN300 device is identical to that of the predicate Babyroo TN300 device (K230278).
Kangaroo warming mode	The patient is warmed by the parent's body heat instead of the device. Once kangaroo mode has been activated, the device is maintained in manual mode with 30 % of the radiant warmer power. During kangarooing, the patient's temperature is monitored continuously.	The patient is warmed by the parent's body heat instead of the device. Once kangaroo mode has been activated, the device is maintained in manual mode with 30 % of the radiant warmer power. During kangarooing, the patient's temperature is monitored continuously.	**Same –** The subject Babyroo TN300 device incorporates the identical kangaroo warming mode as the predicate Babyroo TN300 device.
Skin temperature measuring range	13°C to 43°C (55.4° F to 109.4° F)	13°C to 43°C (55.4° F to 109.4° F)	**Same –** The skin temperature measurement range of the subject Babyroo TN300 device is identical to that of the predicate Babyroo TN300 device (K230278).
Skin Temperature Measurement Accuracy	Overall Accuracy: ± 0.3° C (0.54° F)	Overall Accuracy: ± 0.3° C (0.54° F)	**Same –** The skin temperature measurement accuracy of the subject Babyroo TN300 device is identical to that of the predicate Babyroo TN300 device (K230278).
Skin Temperature Display	0.1°	0.1°	**Same –** The skin temperature display resolution of the subject Babyroo TN300 device is the identical to that of the predicate Babyroo TN300 device (K230278).

	Subject Device	Predicate Device	Comment
	Babyroo TN300 (K243606)	**Babyroo TN300 (K230278)**	
System Specifications			
Resuscitation Module (option)			
Primary patient outlet adjustable airway pressure limit	0 cmH_2O to 40 cmH_2O	0 cmH_2O to 40 cmH_2O	**Same –** The subject Babyroo TN300 device incorporates the same optional resuscitation module as the predicate Babyroo TN300 device (K230278).
Primary patient outlet fixed airway pressure limit	50 cmH_2O ± 10%	50 cmH_2O ± 10%	
Primary Patient Outlet Flow Control Range	0 L/min. to 15 L/min.	0 L/min. to 15 L/min.	
Auxiliary Supply Pressure Limit	75 cmH_2O ± 10%	75 cmH_2O ± 10%	
Blender Module Adjustable O_2 Concentration	21 % to 100 %	21 % to 100 %	
Resuscitation Module AutoBreath® function (option)			
Operating principle	Gas powered, continuous flow, time cycled breaths per minute, pneumatically driven logic circuit.	Gas powered, continuous flow, time cycled breaths per minute, pneumatically driven logic circuit.	**Same –** The subject Babyroo TN300 device incorporates the same optional resuscitation module with AutoBreath® functionality as the predicate Babyroo TN300 device (K230278).
I:E Ratio	Non-adjustable. Fixed internally at 1:2 nominal (1:1.6 to 1:2.4).	Non-adjustable. Fixed internally at 1:2 nominal (1:1.6 to 1:2.4).	

	Subject Device Babyroo TN300 (K243606)	Predicate Device Babyroo TN300 (K230278)	Comment
System Specifications			
Resuscitation module AutoBreath® function (continued)			
Adjustable PEEP	< 2 cmH2O (at 5 L/min) ≤ 4 cmH2O (at 10 L/min) > 14 cmH2O (at 15 L/min)	< 2 cmH2O (at 5 L/min) ≤ 4 cmH2O (at 10 L/min) > 14 cmH2O (at 15 L/min)	**Same –** The subject Babyroo TN300 device incorporates the same optional resuscitation module with AutoBreath® functionality as the predicate Babyroo TN300 device (K230278).
Suction (with optional Resuscitation Module)			
Suction Circuit Adjustable Suction Pressure	0 kPa to 20 kPa (0 mmHg to 150 mmHg)	0 kPa to 20 kPa (0 mmHg to 150 mmHg)	**Same –** The subject Babyroo TN300 device incorporates the same optional resuscitation module with AutoBreath® functionality (including suction) as the predicate Babyroo TN300 device (K230278).
Suction Circuit Maximum Flow Rate	< 20 L/min.	< 20 L/min.	
AutoThermo Package (option)			
AutoThermo SW Package option.	Allows the use of “Tolerate cooling” and “warm-up” functions.	Allows the use of “Tolerate cooling” and “warm-up” functions.	**Same –** The AutoThermo SW package option in the subject Babyroo TN300 device is the same optional feature as that of the predicate Babyroo TN300 device (K230278).
Tolerate cooling function	The device switches to manual mode with switched off radiant warmer. Although all heat sources are switched off, the skin temperature is still monitored continuously.	The device switches to manual mode with switched off radiant warmer. Although all heat sources are switched off, the skin temperature is still monitored continuously.	
Warm-up function	The patient can be warmed in small steps. When warm-up is activated, the device switches to skin temperature mode. The device is operated with the skin temperature settings from the previously set mode.	The patient can be warmed in small steps. When warm-up is activated, the device switches to skin temperature mode. The device is operated with the skin temperature settings from the previously set mode.	
APGAR Timer			
APGAR Timer Function	– Tone is emitted after one minute, after 5 minutes, and 10 minutes. – Timer counts up to 99:59 minutes.	– Tone is emitted after one minute, after 5 minutes, and 10 minutes. – Timer counts up to 99:59 minutes.	**Same –** The subject Babyroo TN300 device and the predicate Babyroo TN300 device (K230278) incorporate the same APGAR timer functionality.

	Subject Device	Predicate Device	Comment
	Babyroo TN300 (K243606)	**Babyroo TN300 (K230278)**	
System Specifications			
SpO_2 Display (option)			
Display of Pulse Oximetry Data	**Facilitates the display of pulse oximetry information via connection to the existing, cleared Draeger Infinity Mcable SET® connection interface (which contains existing, cleared OEM Masimo SET® pulse oximetry technology board) and existing, cleared OEM Masimo SpO_2 sensors.**	**N/A**	**Different –** The subject of this premarket notification is the modification of the Babyroo TN300 device, originally cleared in K230278, to enable functionality in the US market for the display of pulse oximetry information through the connection of the subject device with existing, cleared OEM pulse oximetry accessories. In support of substantial equivalence, verification testing with respect to conformity to ISO 80601-2-61:2017 is included. In addition, verification testing that confirms the effective transfer of the data generated by the OEM pulse oximetry devices is included in this premarket notification in support of substantial equivalence.
SpO_2 Alarms	**Facilitates the setting of SpO_2 alarms for:** **- Upper limit for SpO_2** **- Lower limit for SpO_2** **- Lower alarm limit for desaturation** **- Upper alarm limit for pulse rate** **- Lower alarm limit for pulse rate**	**N/A**	
Physical Attributes			
Bed-tilt	Continuous ± 15° from horizontal. Tactile detents at 0° and ± 10°.	Continuous ± 15° from horizontal. Tactile detents at 0° and ± 10°.	**Same –** The subject Babyroo TN300 device and the predicate Babyroo TN300 device (K230278) incorporate the same patient bassinet assembly and the same bed-tilt functionality.
Height adjustment	Available in fixed and variable height versions.	Available in fixed and variable height versions.	**Same –** The subject Babyroo TN300 device and the predicate Babyroo TN300 device (K230278) incorporate the same patient fixed and variable height features.

	Subject Device Babyroo TN300 (K243606)	Predicate Device Babyroo TN300 (K230278)	Comment
System Specifications			
External Interfaces			
External Interfaces	**OEM SpO_2 connection interface.**	**N/A**	**Different** –The subject device features the SpO_2 connection interface to facilitate connection with the existing, cleared OEM pulse oximetry accessory. As described in the "SpO_2 Display" section of this comparison table, verification testing with respect to conformity to ISO 80601-2-61:2017 as well as verification testing that confirms the effective transfer of the data generated by the OEM pulse oximetry devices is included in this premarket notification in support of substantial equivalence. In addition, cybersecurity assessment of external interfaces, including the SpO_2 interface, is included in support of substantial equivalence.
	USB interface: Connection for mass storage media for importing / exporting of device configurations.	USB interface: Connection for mass storage media for importing / exporting of device configurations.	**Same** – The subject Babyroo TN300 device and the predicate Babyroo TN300 device (K230278) feature the same USB storage interface, RJ45 service port interface, and nurse call interface.
	Service port: RJ45 interface for specialized service functions.	Service port: RJ45 interface for specialized service functions.	
	Nurse call interface	Nurse call interface	

7. Substantial Equivalence Discussion

The subject Babyroo TN300 device has the same intended use as the predicate Babyroo TN300 (K230278) device. Under regulation 21 CFR 880.5130, both the subject Babyroo TN300 and the predicate Babyroo TN300 (K230278) device are infant radiant warmers intended for the thermoregulation and skin temperature monitoring of infant patients. Both the subject device and the predicate device (K230278) are open care radiant warming devices.

In addition to the thermoregulation of infants, the subject Babyroo TN300 and the predicate Babyroo TN300 device (K230278) include indications for optional resuscitation. Both devices include the same optional resuscitation module to provide emergency respiratory support administered by the clinician to newborns.

The subject Babyroo TN300 incorporates the identical radiant heating element as that of the Babyroo TN300 predicate device (K230278). The radiant power (irradiance) specifications and warming modes remain in the subject device as compared to predicate device (K230278).

With the exception of the enabling of existing functionality to display SpO2 information generated by existing, cleared OEM pulse oximetry accessories, all other features and functionality in the subject Babyroo TN300 device are identical to the predicate Babyroo TN300 device (K230278).

The sole modification and only difference between the subject Babyroo TN300 device and the predicate Babyroo TN300 device (K230278) that is introduced in the scope of this premarket notification is the enabling of the SpO2 display functionality.

Verification testing conducted on the subject Babyroo TN300 device has been included in support of substantial equivalence.

8. Non-clinical Performance Testing

The subject Babyroo TN300 was tested in accordance with applicable standards, guidance, and internal design requirements, including performance testing and functional/operation testing. Testing included the cleared OEM accessories that are relevant to the modification that is the subject of this premarket notification. The results of the non-clinical performance testing support substantial equivalence.

The non-clinical performance testing and documentation included in support substantial equivalence consisted of:

- Electromagnetic Compatibility: Conformity assessment according to IEC 60601-1-2: *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*.
- Electrical, Thermal, and Mechanical Safety: Conformity assessment according to IEC 60601-1: *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.*
- Software Documentation: Developed according to processes conforming to IEC 62304: *Medical device software - Software life cycle processes.*
- Software Documentation: With reference to June, 2023, Guidance for Industry and Food and Drug Administration Staff: *Content of Premarket Submissions for Device Software Functions.*
- Software Documentation: With reference to August, 2023, Guidance for Industry and Food and Drug Administration Staff: *Off-The-Shelf*

Software Use in Medical Devices

- Software Documentation: With reference to September, 2023, Guidance for Industry and Food and Drug Administration Staff: *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*
- ISO 80601-2-61:2017, COR1:2018: *Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*
- OEM Integration Validation: Validation of the effective transfer of pulse oximetry signals generated by a clinical simulator through the cleared OEM Masimo SET® pulse oximetry technology board to the subject Babyroo TN300 device's display.

9. Clinical Performance Testing

No human clinical data are included in support of substantial equivalence.

10. Conclusion Regarding Substantial Equivalence

The subject Babyroo TN300 infant radiant warmer device has been compared for the purpose of substantial equivalence to the predicate Babyroo TN300 device which was cleared under premarket notification K230278.

As open care, infant radiant warmers, the subject Babyroo TN300 device and the predicate Babyroo TN300 device (K230278) have the same intended use under regulation 21 CFR 880.5130 (Infant radiant warmer). Both the subject Babyroo TN300 and the predicate Babyroo TN300 device (K230278) are open-care infant radiant warmers intended for the thermoregulation and skin temperature monitoring of infant patients under product code: FMT (Warmer, Infant Radiant).

All warming therapy component designs and warming therapy modes are unmodified as subject to this premarket notification and remain identical to those of the predicate Babyroo TN300 device (K230278). Additionally, the optional integrated scale, heated plate with conductive gel mattress, and emergency resuscitation module features are unmodified in this premarket notification and are identical to the predicate device (K230278).

The indications for use for the subject Babyroo TN300 device are identical to the cleared indications for use of the predicate Babyroo TN300 device (K230278), with the exception of the addition optional pulse oximetry. The addition of the optional pulse oximetry indication is the result of the activation of an existing software feature which was disabled for the US market under the scope of the K230278 clearance.

In support of substantial equivalence, verification testing is included to demonstrate conformity of the subject device – in combination with the cleared OEM pulse oximetry accessories - to the FDA-recognized consensus standard relating to pulse oximetry. Additionally, OEM integration verification testing demonstrating the integrity of the SpO2 information generated by the cleared accessories and displayed by the subject Babyroo TN300 device is included. Software verification and cybersecurity documentation is also provided.

The results of the testing, with the comparison of the intended use, proposed indications for use, technology and features of the subject Babyroo TN300 device to the predicate Babyroo TN300 device (K230278), support a determination of substantial equivalence.