May 30, 2023

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

Re: K230278
Trade/Device Name: Babyroo TN300
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: Class II
Product Code: FMT
Dated: April 28, 2023
Received: April 28, 2023

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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230278

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) 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K230278

1. **Submitter:**

Draeger Medical Systems, Inc.
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Contact Person:

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Date prepared: 30 May 2023

2. **Device:**

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

3. Predicate Devices

The predicate device that has been identified relating to the substantial equivalence of the Babyroo TN300 device are:

Predicate Devices:

Predicate Device	510(k)	Manufacturer
Resuscitaire® with AutoBreath®	K120642	Draeger Medical Systems, Inc.

The following reference device is utilized in support of substantial equivalence.

Reference Device	510(k)	Manufacturer
Babyleo TN500	K182859	Drägerwerk AG & Co. KGaA

4. Device Description

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 pneumatic 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) 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.

6. List of Consensus Standards

Standard Number and Version	Title
IEC 60601-1:2005/A1:2012/ COR1:2014	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6: 2010/A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1:2015 COR 1 2016	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 60601-1-8:2006/A1:2012	Medical Electrical Equipment, Part 1-8: General Requirements for Basic Safety and Essential Performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304:2006/A1:2015	Medical device software - Software life cycle processes
IEC 60601-2-21:2009/A1:2016	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
IEC 80601-2-35:2009/A1:2016	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use
ISO 10079-3:2014	Medical suction equipment -- Part 3: Suction equipment powered from a vacuum or pressure gas source
IEC 10651-5:2006	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 5: Gas-powered emergency resuscitators
ISO 18562-1:2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 17664:2017	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices

7. Substantial Equivalence Comparison and Discussion

	Predicate Device	Proposed Device	Comment
	Resuscitaire® with AutoBreath (K120642)	**Babyroo TN300**	
Regulation	880.5130	880.5130	**Same –** The proposed device and the predicate device (K120642) are Class II devices regulated under 880.5130 (product code: FMT).
Product Code	FMT	FMT	
Classification	II	II	
Indications for Use	The Resuscitaire® Radiant Warmer is intended for thermoregulation, skin temperature monitoring, APGAR timing and resuscitation of newly born infants up to 10 kg. It is not for long term resuscitation or home 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) 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.	**Same –** The proposed device and the predicate device are both primarily intended for use for the thermoregulation of infant patients with the inclusion of resuscitation (optional in both cases). The weight limitation (10 kg) for the proposed device, is identical to the primary predicate device (K120642) and is established in the proposed device contraindications. While not stated in the cleared indications, weighing functionality in the predicate device (K120642) and APGAR timing in the proposed device are present.
Contraindications	The Resuscitaire Radiant Warmer is not intended for home use or long-term resuscitation.	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.	

	Predicate Device	Proposed Device	Comment
	Resuscitaire® with AutoBreath (K120642)	**Babyroo TN300**	
Environment of Use	For use in any location within a health care facility where labor and delivery may occur.	For use in labor and delivery units, neonatal intensive care units, operating rooms, and during intra-hospital transfer where some of the functions described in the intended use description are not available.	**Same –** The intended environments of use for the predicate device (K120642) is inclusive of those for the proposed device.
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 proposed device is the same as that of the primary predicate device (K120642).
Irradiance	30% power – 10 mW/cm^2	30% power – 10 mW/cm^2 60% power – 18 mW/cm^2 100% power – 32 mW/cm^2	**Same –** The proposed device features the same irradiance at 30% power as the predicate device (K120642).
Pre-warm Procedure	Power Duration 1. 100% 3 min. 2. 60% 12 min. 3. 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 proposed device incorporates the same power sequence during pre-warm as the predicate device (K120642).
Warming Therapy Modes	- Skin temperature mode - Manual mode	- Skin temperature mode - Manual mode - Kangaroo mode	**Different –** The warming therapy modes offered in the predicate device (K120642) include skin temperature mode and manual mode. Kangaroo mode is not present in the predicate device (K120642). However, the underlying questions of safety and effectiveness are not affected as both device have warming features and the verification of requirements relating to Kangaroo mode in the proposed Babyroo TN300 device is included in support of substantial equivalence.
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 proposed device is identical to that of the predicate device (K120642).

	Predicate Device	Proposed Device	Comment
	Resuscitaire® with AutoBreath (K120642)	**Babyroo TN300**	
Manual warming mode	Radiant warmer power is set manually. After the user sets the radiant warmer power, a timer starts: – After 10 minutes the "**Check patient**" alarm is displayed. – After 15 minutes, the radiant warmer is switched off.	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 specification in the predicate device (K120642) is inclusive of that of the proposed devicee.
Kangaroo warming mode	N/A	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.	**Different –** The proposed device incorporates kangaroo warming mode, which is not present in the predicate device (K120642). While the predicate device (K120642) does not incorporate Kangaroo mode, the underlying questions of safety and effectiveness are not affected as both devices have warming features and the verification of requirements relating to Kangaroo mode in the proposed Babyroo TN300 device is included in support of substantial equivalence.
Skin temperature measuring range	18°C to 43°C (64.4° F to 109.4° F)	13°C to 43°C (55.4° F to 109.4° F)	**Different –** The skin temperature measurement range of the proposed device is inclusive of that of the predicate device (K120642).
Skin Temperature Measurement Accuracy	Display Accuracy: ± 0.2°C	Overall Accuracy: ± 0.3° C (0.54° F)	**DIfferent –** The skin temperature measurement display accuracy of the proposed device is slightly different than the predicate device (K120642) Verification testing included in support of substantial equivalence demonstrates that underlying questions of safety and effectiveness are not affected .
Skin Temperature Display	0.1°	0.1°	**Same –** The skin temperature display resolution of the proposed device is the same as that of the predicate device (K120642).

	Predicate Device	Proposed Device	Comment
	Resuscitaire® with AutoBreath (K120642)	**Babyroo TN300**	
Primary patient outlet adjustable airway pressure limit	0 cmH_2O to 50 cmH_2O	0 cmH_2O to 40 cmH_2O	**Different –The** maximum airway pressure of the proposed device does not exceed that of the predicate device (K120642). Typical airway pressures are administered at < 30 cm H_2O. In some cases, >30 to 40 cm H_2O may be required for patients without spontaneous ventilation. As recommended by the American Academy of Pediatrics (AAP)[1]
Primary patient outlet fixed airway pressure limit	50 cmH_2O ± 10%	50 cmH_2O ± 10%	**Same –** The proposed device's primary patient outlet fixed airway pressure limit is identical to that of the predicate device (K120642).
Primary Patient Outlet Flow Control Range	0 L/min. to 15 L/min.	0 L/min. to 15 L/min.	**Same –** The proposed device's primary patient outlet Flow Control Range is identical to that of the predicate device (K120642).
Auxiliary Supply Pressure Limit	160 cmH_2O ± 10%	75 cmH_2O ± 10%	**Different –T**he maximum auxiliary supply pressure limit of the proposed device does not exceed the predicate device (K120642). Typical airway pressures are administered at < 30 cm H_2O. In some cases, $\geq$30 to 40 cm H_2O may be required for patients without spontaneous ventilation. As recommended by the American Academy of Pediatrics (AAP)[1]
Blender Module Adjustable O_2 Concentration	21 % to 100 %	21 % to 100 %	**Same –** The proposed device's adjustable O_2 concentration range identical to that of the predicate device (K120642).
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 proposed device's optional AutoBreath® functionality is identical to that of the predicate device (K120642).
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)	**Same –** The proposed device's I:E ratio for its AutoBreath® functionality is identical to that of the predicate device (K120642).

	Predicate Device	Proposed Device	Comment
	Resuscitaire® with AutoBreath (K120642)	**Babyroo TN300**	
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 proposed device's adjustable PEEP characteristics for its AutoBreath® functionality is identical to that of the predicate device (K120642).
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 proposed device provides the same suction pressure range as the predicate device (K120642).
Suction Circuit Maximum Flow Rate	< 20 L/min.	< 20 L/min.	**Same –** The proposed device provides the same suction maximum flow rate as the predicate device (K120642).
AutoThermo SW Package option.	N/A	Allows the use of "Tolerate cooling" and "warm-up" functions.	**Different –** The proposed device incorporates optional AutoThermo functions, which are not present in the predicate device (K120642). While the predicate device (K120642) does not incorporate these features, the underlying questions of safety and effectiveness are not affected as both device have warming features and the verification of requirements relating to the AutoThermo function in the proposed Babyroo TN300 device is included in support of substantial equivalence.
Tolerate cooling function	N/A	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	N/A	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 Function	– Tone is emitted after one minute, after 5 minutes, and 10 minutes. – Timer counts up to 59:59 minutes.	– Tone is emitted after one minute, after 5 minutes, and 10 minutes. – Timer counts up to 99:59 minutes.	**Same –** The proposed device, as well as the predicate device (K120642) features an APGAR timer function.

	Predicate Device	Proposed Device	Comment
	Resuscitaire® with AutoBreath (K120642)	**Babyroo TN300**	
Bed-tilt	± 10° from horizontal	Continuous ± 15° from horizontal. Tactile detents at 0° and ± 10°.	**Different –** The proposed device, as well as the predicate device (K120642) include bed-tilt capability. Testing is included to verify the requirements of the bed-tilt specifications of the proposed device and the results support substantial equivalence.
Height adjustment	Available in fixed and variable height versions.	Available in fixed and variable height versions.	**Same –** The proposed, as well as the predicate device (K120642) feature versions with adjustable height or include integral height adjustment.
External Interfaces	COM port: serial interface for specialized service functions.	Nurse call interface	**Different –** The proposed device and predicate device (K120642) incorporate external interfaces. Differences in the specific interfaces are addresses with the inclusion of relevant verification testing and analysis in support of substantial equivalence.
		USB interface: Connection of mass storage media for importing / exporting of device configurations.	
		Service port: RJ45 interface for specialized service functions.	

[1]PEDIATRICS Volume 126 Number 5, November 2010

8. Substantial Equivalence Discussion

The subject Babyroo TN300 device has the same intended use as the primary predicate Resuscitaire® with AutoBreath® (K120642). Under regulation 21 CFR 880.5130, both the subject Babyroo TN300 and the predicate device (K120642) are infant radiant warmers intended for the thermoregulation and skin temperature monitoring of infant patients. Both the subject device and the predicate device (K120642) are open care radiant warming devices.

In addition to the thermoregulation of infants, the subject Babyroo TN300 and the predicate devices (K120642) include indications for resuscitation. Both devices include optional resuscitation modules to provide emergency respiratory support administered by the clinician to newborns. Both the subject and predicate (K120642) devices offer the Draeger AutoBreath® functionality in their resuscitation modules. The AutoBreath® functionality automates the resuscitation process by allowing the clinician to set the respiratory rate which is time-cycled by the pneumatically driven logic circuit.

With reference to the July, 2014 Guidance for Industry and Food and Drug Administration Staff: *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*, the Babyleo TN500 device (K182859) is included as a reference device in support of the substantial equivalence of the subject Babyroo TN300. Specifically, the reference device (K182859) is utilized to support the previously demonstrated substantial equivalence of technological features in the subject device that are not present in the primary predicate device (K120642). The reference device is utilized to leverage the test methods for these new features.

As summarized in the "Non-clinical Performance Testing" section of this 510(k) Summary, testing according to the requirements of FDA-recognized consensus standards was conducted on the subject device and included in this premarket notification. The tests were conducted to confirm that the specific design of the subject device relating to its essential performance meets the requirements of the consensus FDA-recognized standards. The results of the testing demonstrated that the subject device conforms to the requirements of the standards and support substantial equivalence.

9. Non-clinical Performance Testing

The subject Babyroo TN300 was tested in accordance with applicable standards, guidance, and internal design requirements, including performance testing, functional/operation testing, biocompatibility, human factors, risk analysis and verification of risk control measures. Testing included accessories and optional components. The results of the non-clinical performance testing support substantial equivalence.

The performance test data were provided to support substantial equivalence included:

- IEC 60601-1:2005/A1:2012/ COR1:2014: *Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2:2014: *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- IEC 60601-1-6: 2010/A1:2013: *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
- IEC 62366-1:2015 COR 1 2016: *Medical devices - Part 1: Application of usability engineering to medical devices*
- Human Factors Testing: With reference to February, 2016, Guidance for Industry and Food and Drug Administration Staff: *Applying Human Factors and Usability Engineering to Medical Devices*

- IEC 62304:2006/A1:2015: *Medical device software - Software life cycle processes*
- Software Documentation: With reference to November, 2021, Draft Guidance for Industry and Food and Drug Administration Staff: *Content of Premarket Submissions for Device Software Functions*
- Software Documentation: According to September, 2019, Guidance for Industry and Food and Drug Administration Staff: *Off-The-Shelf Software Use in Medical Devices*
- Software Documentation: With reference to April, 2022, Draft Guidance for Industry and Food and Drug Administration Staff: *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*
- IEC 60601-2-21:2009/A1:2016: *Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers*
- IEC 80601-2-35:2009/A1:2016: *Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use*
- IEC 10651-5:2006: *Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 5: Gas-powered emergency resuscitators*
- ISO 10079-3:2014: *Medical suction equipment -- Part 3: Suction equipment powered from a vacuum or pressure gas source*
- ISO 10993-1:2018: *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*
- ISO 18562-1:2017-03: *Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process*
- ISO 17664:2017: *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices*

10. Clinical Performance Testing

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

11. Conclusion Regarding Substantial Equivalence

The information included in this premarket notification supports the substantial equivalence of the subject Babyroo TN300. As regulated under 21 CFR 880.5130, the subject device has the identical intended use as the legally marketed primary predicate device cleared under premarket notification K120642. While the proposed indications for use for the subject device are not identical to the primary predicate device (K120642), conformity assessment test data are included to support the conformity of the differences.

Performance and software data are included in this premarket notification to demonstrate that the subject Babyroo TN300 device meets its design, functional, and safety

requirements. The results of the testing included in this premarket notification, in conjunction with the comparison to the fundamental intended use and fundamental technology of the subject device to that of the primary predicate device (K120642) support a determination of substantial equivalence.