February 13, 2026

Drägerwerk AG & Co KGaA
Lyubov Lange
Regulatory Affairs Manager
Moislinger Allee 53-55
Schleswig-Holstein
Luebeck, 23542
Germany

Re: K251619
Trade/Device Name: Babyleo TN500
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal incubator
Regulatory Class: Class II
Product Code: FMZ, FMT
Dated: January 15, 2026
Received: January 15, 2026

Dear Lyubov Lange:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

DAVID WOLLOSCHECK -S

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251619

Device Name
Babyleo TN500

Indications for Use *(Describe)*
The Babyleo TN500 is intended for use with neonates and infants and can be used as both an incubator and a radiant warmer. When the product is switched between incubator and radiant warmer operation, patients continue to be kept warm during the transition. It enables the controlled warming of patients with a body weight of up to 10 kg (22 lbs). The device can be operated as either a closed care unit or an open care unit. As a closed care unit, Babyleo TN500 is an incubator. Neonates and infants are kept warm in the patient compartment with humidifiable air which can be enriched with oxygen (option). As an open care unit, Babyleo TN500 is a radiant warmer.
The Babyleo TN500 provides controlled ambient conditions for neonates and infants. The following parameters are regulated, according to the intended use:
– Temperature
– Humidity
– Oxygen (option)

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K251619

Submitter: Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck, Germany
Establishment's registration number: 9611500

Contact Person: Dr. Lyubov Lange
telephone number: +49 451 882- 3247
e-mail address: lyubov.lange@draeger.com
address: Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck, Germany

Date prepared: February 9, 2026

Device Name:

Trade name:	Babyleo TN500
Common name:	Neonatal Incubator
Classification name:	Neonatal Incubator
Regulation number:	21 CFR § 880.5400
Product code:	FMZ/FMT
Class:	II

Predicate device: Babyleo TN500, K182859

Common name:	Neonatal Incubator
Classification name:	Neonatal Incubator
Regulation number:	21 CFR § 880.5400
Product code:	FMZ/FMT
Class:	II

Drägerwerk AG & Co. KGaA is submitting a traditional 510(k) premarket notification for a modification to an existing device, the Babyleo TN500 neonatal incubator, previously cleared under K182859. In support of substantial equivalence, the Babyleo TN500, cleared under K182859 has been identified as the predicate device for this premarket notification.

Purpose of the premarket notification

The purpose of this traditional 510(k) premarket notification is to modify the Dräger Babyleo TN500 device. Dräger currently has market clearance for the device Babyleo TN500 via special 510(k) K182859 which serves as the predicate device in the present submission. The first clearance for Babyleo TN500 was K162821 (traditional 510(k)). The following list outlines the technological characteristics that are the same or similar as those of the predicate device (K182859):

- Radiant warmer operation including:
  - Manual mode
  - Skin temperature regulation
- Incubator operation including:
  - Humidification
  - Oxygen supply (option)
  - Air temperature regulation
  - Skin temperature regulation
- Scale (option)
- Heated, x-ray transparent mattress (option)
- Height adjustment of the device
- Inclination of the mattress tray
- Optical and acoustical alarm system including power supply failure alarm
- Data exchange interfaces

The technological characteristic that differs from the predicate device (K182859) is the integrated battery (option) that supports intrahospital patient transport in incubator operation.

The software has been updated as well and the new software version 2.01.00 facilitates functionality for intrahospital patient transport with the battery. Additionally, the software version 2.01.00 contains enhancements of the control software, extended cybersecurity improvements, and a new processor board M48.

The change from processor board M16 in the predicate device to processor board M48 in the subject device was needed to enable the extended cybersecurity improvements. M48 comes with higher performance, it is operated with a cooling fan. The changed electrical interface of M48 caused an adaptation of the main board.

Another modification that is subject of this premarket notification is the biocompatibility relevant change of the bed support and the scale. The base material of the bed support

and the scale is the same. In the predicate device, the patient bed parts, and the scale were lacquered. The lacquer is now omitted.

Device Description

Babyleo TN500 is a warming therapy device intended to provide controlled conditions in the microenvironment for neonates and infants. Such conditions are characterized by the physical properties temperature, humidity, and oxygen.

Intended to be a hybrid device, Babyleo TN500 can be operated as an incubator (according to IEC60601-2-19) or as a radiant warmer (according to IEC60601-2-21).

Babyleo TN500 provides three heat sources:

- the radiant warmer,
- the convective heater and
- the heated mattress (option).

The three heat sources are synchronized to keep the temperature stable. If the optional heated mattress is not present, the patient bed is formed by the SoftBed mattress.

The radiant warmer is mounted at the top of the main column. Thus, in radiant warmer operation, it enables the radiant heat to reach the patient bed where the infant is lying.

The patient compartment is bounded by the hood and lateral walls surrounding the patient bed. The hood is connected to the main column via the hood arm and can be opened manually. When closing the hood, the device switches automatically from radiant warmer to incubator operation.

In incubator operation the convective heater, which is located in the aggregate housing underneath the patient bed, provides warm air. Both, in radiant warmer and in incubator operation the optional heated mattress additionally warms the infant conductively.

Patient compartment, aggregate housing and main column are mounted on the trolley. By means of foot pedals located on each side of the device the user can control a lifting column and adjust the height of the patient compartment. Four double-wheel casters and handles allow to move the Babyleo TN500.

An optional rechargeable battery integrated into the trolley feeds the convective heater for a limited time in incubator operation when mains supply is not available. Thus, intra-hospital transport of the device in incubator operation is enabled.

For routine care interventions in incubator operations the patient compartment provides hand ports which automatically open if the corresponding hand port locks are pushed

down. For larger interventions the access panels can be opened by lifting them and folding them down. Furthermore, the patient compartment obtains hose grommets to conduct hoses or lines into the patient compartment.

An optional electronic scale is integrated into the Babyleo TN500 to weigh the patient. In the optional integrated drawer items needed for the patient care can be stored.

In incubator operation the air inside the patient compartment can be humidified and enriched with oxygen. For humidification distilled water is provided via the Luer Lock connector to the humidification system where it is evaporated and delivered into the breathing gas.

The optional oxygen regulation provides oxygen enrichment for the breathing gas. It can either be fed by the central gas supply or by oxygen cylinders.

Indications for Use

The Babyleo TN500 is intended for use with neonates and infants and can be used as both an incubator and a radiant warmer. When the product is switched between incubator and radiant warmer operation, patients continue to be kept warm during the transition. It enables the controlled warming of patients with a body weight of up to 10 kg (22 lbs). The device can be operated as either a closed care unit or an open care unit. As a closed care unit, Babyleo TN500 is an incubator. Neonates and infants are kept warm in the patient compartment with humidifiable air which can be enriched with oxygen (option). As an open care unit, Babyleo TN500 is a radiant warmer.

The Babyleo TN500 provides controlled ambient conditions for neonates and infants. The following parameters are regulated, according to the intended use:

- Temperature
- Humidity
- Oxygen (option)

Substantial Equivalence Comparison and Discussion

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
Manufacturer	Drägerwerk AG & Co. KGaA	Drägerwerk AG & Co. KGaA	Same
510(k) number	K251619	K182859	-
Regulation number	880.5400	880.5400	Same
Classification description	Incubator, neonatal	Incubator, neonatal	Same
Regulatory class	Class II	Class II	Same
Product code	FMZ/FMT	FMZ/FMT	Same
Patient population	Neonates and infants	Premature babies and neonates	Same The patient population has been clarified. The terms "neonate" and “infant” for the proposed device have been defined in the indications for use more specifically to align with the identification of pediatric subgroups in FDA Guidance for Industry and Food and Drug Administration Staff: *Premarket Assessment of Pediatric Medical Devices.*

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
Indications for Use	The Babyleo TN500 is intended for use with neonates and infants and can be used as both an incubator and a radiant warmer. When the product is switched between incubator and radiant warmer operation, patients continue to be kept warm during the transition. It enables the controlled warming of patients with a body weight of up to 10 kg (22 lbs). The device can be operated as either a closed care unit or an open care unit. As a closed care unit, Babyleo TN500 is an incubator. Neonates and infants are kept warm in the patient compartment with humidifiable air which can be enriched with oxygen (option). As an open care unit, Babyleo TN500 is a radiant warmer. The Babyleo TN500 provides controlled ambient conditions for neonates and infants. The following parameters are regulated, according to the intended use: - Temperature - Humidity - Oxygen (option)	Babyleo TN500 is intended for use with premature babies and neonates and can be used as both an incubator and a radiant warmer. When the product is switched between incubator and radiant warmer operation, patients continue to be kept warm during the transition. The device provides a thermally regulated environment for patients with a body weight of up to 5 kg (11 lbs) and a height of up to 55 cm (22 in). The device can be operated as either a closed care unit or an open care unit. As a closed care unit, Babyleo TN500 is an incubator. Neonates are kept warm in the patient compartment with humidifiable air, which can be enriched with oxygen (option). As an open care unit, Babyleo TN500 is a radiant warmer. Babyleo TN500 provides controlled ambient conditions for premature babies and neonates. The following parameters are regulated, according to the intended use: – Temperature – Humidity – Oxygen (option)	Different • Editorial change from “The device provides a thermally regulated environment for patients…” to “It enables the controlled warming of patients”. • Change from “up to 5kg (11 lbs) and a height of up to 55 cm (22 in.)” to “up to 10 kg (22 lbs)” • Change from “premature babies and neonates” to “neonates and infants”.

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
Environments of use	Babyleo TN500 provides controlled ambient conditions for neonates and infants in a hospital. Babyleo TN500 is intended for use in the following environments: – Labor and delivery units – Labor and delivery rooms – Neonatal intensive care units – Operating rooms The following ambient conditions must be met for stationary use and transport: – Temperature 20 to 35 °C (68 to 95 °F) – Relative humidity 20 to 95 %, non-condensing – Air flow in air-conditioned rooms max. 0.3 m/s (11.8 in/s)	Babyleo TN500 provides controlled ambient conditions for premature babies and neonates in a hospital. Babyleo TN500 is intended for use in the following environments: – Labor and delivery units – Labor and delivery rooms – Neonatal intensive care units – Operating rooms	Same The same ambient conditions as those of the predicate device - as defined in the “Technical data” section of the predicate device (K182859) Instructions for Use (IFU) - are now also included under Environments of Use for the subject device. While the same conditions are also defined in the “Technical data” section of the subject device IFU, these ambient conditions are included with the environments of use to further clarify that the subject device is intended for use only within controlled hospital environments and cannot be used as a transport device outside of hospital conditions.

Environments of use (continued)	Babyleo TN500 is intended for intrahospital transport with restricted intended use. Intrahospital transport is considered as movement of Babyleo TN500 between defined care areas within a hospital building (examples include but are not limited to: labor and delivery units, labor and delivery rooms, neonatal intensive care units, radiology departments, and operating rooms). The following restrictions apply for intrahospital patient transport with battery (option): – Babyleo TN500 is not intended for use outside a hospital building or in any area where fluctuations in temperature, exposure to water, or environmental climate conditions other than the above specified may occur. – Radiant warmer operation is not possible. – Active humidification is switched off. The patient is supplied with the existing humidity. The humidity continues to be measured. – The patient's state of health must be suitable for transport. – Babyleo TN500 is tested per IEC 60601-2-20 for intrahospital transport.	Babyleo TN500 is intended for use in the following environments where some of the functions described under intended use are restricted (no active warming therapy, humidification, and oxygen enrichment). For further information, see the following chapter: ''Intrahospital patient transfer with switched off warming therapy'' (page 152) – During intrahospital patient transfer	Different: intrahospital patient transport with battery (option) is added to the subject device's Environments of Use. Specifically identified transport environments indicated for the subject device added. Restrictions applicable for intrahospital patient transport with battery (option) clarified. Comparison of "intrahospital transport with the device switched off" ("intrahospital patient transfer") with "intrahospital transport with battery (option)": • same: Intrahospital **transport/transfer** • same: Radiant warmer operation is not possible • same: Active humidification is switched off. The patient is supplied with the existing humidity. • different: The humidity continues to be measured during "intrahospital transport with battery (option)" • different: Active warming therapy via incubator operation is possible during "intrahospital transport with battery (option)" • different: The patient is actively provided with oxygen during "intrahospital transport with battery (option)" The changed environments of use for the subject device are supported by testing per

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
	Observe the following information:" Transport with battery (option)", page 131.		IEC 60601-2-19 and IEC 60601-2-20 for intrahospital transport.
	The following restrictions apply for intrahospital patient transport with the device switched off: – Babyleo TN500 is not intended for use outside a hospital building or in any area where fluctuations in temperature, exposure to water, or environmental climate conditions other than the above specified may occur. – The warming therapy is switched off. – During transport, the patient is not actively provided with heat, humidified air, and oxygen. – The body core temperature of the patient must be monitored with an external temperature sensor. – The patient's state of health must be suitable for transport. – Babyleo TN500 is tested per IEC 60601-2-20 for intrahospital transport. Observe the following information: "Transport with device switched off, page 141.	Babyleo TN500 is intended for use in the following environments where some of the functions described under intended use are restricted (no active warming therapy, humidification, and oxygen enrichment). For further information, see the following chapter: ''Intrahospital patient transfer with switched off warming therapy'' (page 152)* – During intrahospital patient transfer *page 152 of IFU_February_2022_Predicate_Device	Different The designation “**intrahospital patient transfer**” used in the predicate device’s IFU has been **reworded to “intrahospital transport with the device switched off”** for the subject device. Restrictions applicable for intrahospital patient transport with the device switched off clarified. The changed environments of use for the subject device are supported by testing per IEC 60601-2-19 and IEC 60601-2-20 for intrahospital transport.

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
Environments of use (continued)	Babyleo TN500 is not intended for use in the following environments: – Home use – MRI environment – Transport vehicles, e.g., ambulances, airplanes, or helicopters – Babyleo TN500 is not intended for use outside a hospital building or in any area where fluctuations in temperature, exposure to water or environmental climate conditions other than the above specified may occur. – Babyleo TN500 is tested per IEC 60601-2-20 for intrahospital transport.	Babyleo TN500 is not intended for use in the following environments: – Home use – Transport vehicles, e.g., ambulances, airplanes, or helicopters – MRI environment	Different Transport environments which are not indicated for the subject device are added/clarified.
Technical Data			
Operating characteristics			
Power supply			
Mains power connection	100 V to 240 V 50/60 Hz	100 V to 240 V 50/60 Hz	Same
Maximum current consumption/ power consumption	10 A/1000 W	10 A/1000 W	Same

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
Processor board	New processor board M48 with fan and adaption on the main board	Processor board M16	Different Supported by testing per IEC 60601-2-19, IEC 60601-2-21, IEC 60601-1, IEC 60601-1-2, and bench performance testing: verification of technical data, device behavior and device performance.
Batteries (option) Type: LiFePO4 battery with battery management system Fuse: F15A 80V UL248			
--	The battery runtime applies for new and fully charged batteries for typical warming therapy. The battery runtime depends on the usage scenario. Low ambient temperatures can shorten the battery runtime.	n/a	Different Supported by bench performance testing: battery testing in typical operation.
	The charging time applies for new and fully discharged batteries for typical warming therapy. The actual charging time depends on the actual battery charge.	n/a	Different Supported by bench performance testing: testing of battery charging time.

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
	Typical warming therapy in incubator operation Air temperature: 35 °C (95 °F) Ambient temperature: 24 °C (75 °F)	n/a	Different Supported by bench performance testing: battery testing in typical operation.
Battery runtime	45 minutes	n/a	Different Supported by bench performance testing: battery testing in typical operation.
Battery charge time	240 minutes	n/a	Different Supported by bench performance testing: testing of battery charging time.
Gas supply (option)			
O2 operating pressure	2.7 to 6.0 bar (or 270 to 600 kPa or 39 to 87 psi)	2.7 to 6.0 bar (or 270 to 600 kPa or 39 to 87 psi)	Same
Height adjustment of the device			
Height adjustment range	400 mm (15.75 in)	400 mm (15.75 in)	Same
Inclination of the mattress tray			
Bed-tilt mechanism	Continuous up to 13° inclination on both sides	Continuous up to 13° inclination on both sides	Same
Performance characteristics			
Operating noise			
Operating volume in patient compartment	Typically 40 dB(A) Measured without oxygen application	Typically 40 dB(A) Measured without oxygen application	Same
Alarm volume			

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
Setting range for high- and medium-priority alarms	≥50 dB(A) to ≤75 dB(A) Measured in accordance with IEC 60601-2-19 and IEC 60601-2-21	≥50 dB(A) to ≤70 dB(A) Measured in accordance with IEC 60601-2-19 and IEC 60601-2-21	Different Safety and efficacy of the acoustic alarm is sustained as alarm sound volume is at least as high as that of the predicate device. The safety and efficacy of the current design are supported by testing per 60601-2-19, IEC 60601-2-21, and bench performance testing: testing of alarm and operation sound level.
Power supply failure alarm			
Alarm volume	≥65 dB(A) to ≤85 dB(A)	65 dB(A)	Different Device behavior is the same, only technical data is refined by providing the upper limit. Thus, the safety and efficacy are not affected. The safety and efficacy of the current design are supported by testing per 60601-2-19 and IEC 60601-2-21.
Duration	10 minutes	10 minutes	Same
Radiant warmer operation			
Radiant flux per area in highest horizontal mattress tray position	At 30 % radiant warmer power ≤10 mW/cm^2 At 60 % radiant warmer power ≥17 mW/cm^2 At 100 % radiant warmer power ≥32 mW/cm^2	At 30% radiant warmer power 10 mW/cm^2 At 60% radiant warmer power 18 mW/cm^2 At 100% radiant warmer power 32 mW/cm^2	Different Correction of the specification information. The safety and efficacy of the current design are supported by bench performance testing: testing of irradiance level and warm-up time.

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
Minimum distance to ceiling and wall	To safely operate the radiant warmer, ensure a distance of at least 20 cm (8 in) at the following positions: - Between the top edge of the radiant warmer and the ceiling - From the side surfaces of the radiant warmer to the wall	To ensure safe operation of the radiant warmer, maintain a distance of at least 20 cm (8 in) between the upper edge of the radiant warmer and the ceiling	Same
Incubator operation			
Warm-up time measured according to IEC 60601-2-19	15 to 20 minutes	15 to 20 minutes	Same
Humidification	Boiling of Aquadest/distilled water	Boiling of Aquadest/distilled water	Same
Flow velocity over mattress surface	10 cm/s (3.94 in/s) (with a horizontal mattress tray and an air temperature of 36 °C (96.8 °F))	10 cm/s (3.94 in/s) (with a horizontal mattress tray and an air temperature of 36 °C (96.8 °F))	Same
Maximum CO_2 concentration in the incubator measured in accordance with IEC 60601-2-19	<0.5 Vol%	<0.5 Vol%	Same
Touch time:			

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
Allows undisturbed patient care for 20 minutes: – Intensifies the air curtain in the device – Suppresses some alarms acoustically and visually	Yes Included in each device	Yes Option	Same
Measured value displays			
Radiant warmer			
Setting range	Off, 10 % to 100 % in steps of 10 %	Off, 10 % to 100 %	Different Technical data is refined by adding the increments (steps). The safety and efficacy of the current design are supported by bench performance testing: testing of radiant heater power level control setting.
Pre-warm mode	100 % for 3 minutes 60 % for 11.5 minutes 30 % until setting is changed	100 % for 3 minutes 60 % for 11.5 minutes 30 % until setting is changed	Same
Air temperature regulation			
Measurement range	13 to 45 °C (55.4 to 113 °F)	13 to 45 °C (55.4 to 113 °F)	Same

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
Measurement uncertainty	±0.8 °C (1.44 °F) (measured without hood cover)	±0.8 °C (1.44 °F)	Different Measurement uncertainty has been specified without hood cover for both predicate and proposed device. The specification in the technical data has now been refined to consider that. The safety and efficacy of the current design are supported by testing per 60601-2-19, and bench performance testing: testing of accuracy of the air temperature.
Setting range	20 to 39 °C (68 to 102.2 °F) in steps of 0.1 °C (0.1 °F) <28 °C (82.4 °F), after confirmation >37 °C (98.6 °F), after confirmation	20 to 39 °C (68 to 102.2 °F) <28 °C (82.4 °F), after confirmation >37 °C (98.6 °F), after confirmation	Different Technical data is refined by adding the increments (steps). The safety and efficacy of the current design are supported by bench performance testing: testing of air temperature control setting range.
Skin temperature regulation			
Measurement range	13 to 43 °C (55.4 to 109.4 °F)	13 to 43 °C (55.4 to 109.4 °F)	Same
Temperature Sensor for Skin	Thermo Trace (Dräger)	Thermo Trace (Dräger)	Same
Measurement uncertainty (sensors)	±0.1 °C (0.18 °F)	± 0.1 °C (0.18 °F)	Same

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
Measurement uncertainty (entire system)	±0.3 °C (0.54 °F)	±0.3 °C (0.54 °F)	Same
Setting range	34 to 38 °C (93.2 to 100.4 °F) in steps of 0.1 °C (0.1 °F) >37 °C (98.6 °F), after confirmation	34 to 38 °C (93.2 to 100.4 °F) >37 °C (98.6 °F), after confirmation	Different Technical data is refined by adding the increments (steps). The safety and efficacy of the current design are supported by. bench performance testing: testing of skin temperature control setting.
Humidifier regulation			
Measurement range	Normal range: 30 to 99 % r. H. Extended range: 10 to 29 % r. H.	Normal range: 30 to 99 % R H Extended range: 10 to 29 % R H	Same
Measurement uncertainty in normal range	±10 %	±10 %	Same
Setting range	Off, 30 to 99 % r. H. in steps of 1 %, Auto	Off, 30 to 99 % r. H. in steps of 1 %, AUTO	Same
2.4 Data exchange and interfaces	Port for central alarm (nurse call) COM port (MEDIBUS.X) USB port (USB type A socket; USB 2.0) Network port (RJ45 connector) Audio port	Port for central alarm (nurse call) COM port (MEDIBUS.X) USB port (USB type A socket; USB 1.1 or USB 2.0) Network port (RJ45 connector) Audio port	Same
Options			
Heated, x-ray transparent mattress			

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
Setting range	Off, 35 to 39 °C (95 to 102 °F) in steps of 0.5 °C (0.5 °F), Auto	Off, 35 to 39 °C (95 to 102 °F), AUTO	Different Technical data is refined by adding the increments (steps). The safety and efficacy of the current design are supported by bench performance testing: testing of heated mattress control setting,
Oxygen regulation in the patient compartment			
Measurement range	Normal range: 18 to 65 Vol% Extended range: 66 to 99 Vol%	Normal range: 18 to 65 Vol% Extended range: 66 to 99 Vol%	Same
Measurement uncertainty in normal range	± (2.5 Vol% + 2.5 % of measured value)	± (2.5 Vol% + 2.5 % of measured value)	Same
Setting range	Off, 21 to 65 Vol% in steps of 1 Vol% >40 Vol%, after confirmation	Off, 21 to 65 Vol% >40 Vol%, after confirmation	Different Technical data is refined by adding the increments (steps). The safety and efficacy of the current design are supported by bench performance testing: testing of oxygen control settings.
O2 rise time from 21 to 65 Vol%	<10 minutes	<10 minutes	Same
Oxygen Cylinder Holder	Yes	Yes	Same
AutoThermo package for advanced therapy applications			
– Tolerate cooling – Warm-up – Weaning	Yes	Yes	Same
Developmental Care package			

Specification	Subject device	Predicate unmodified device	Comments
	Babyleo TN500 (K251619)	Babyleo TN500 (K182859)	
Noise measurement in patient compartment			
Measurement range	40 to 90 dB(A)	40 to 90 dB(A)	Same
Light measurement in patient compartment			
Measurement range	3 to 999 Lux (1 to 93 fc)	3 to 999 Lux (1 to 93 fc)	Same

Substantial Equivalence Discussion

The subject Babyleo TN500 device has the same intended use as the unmodified predicate Babyleo TN500 (K182859) device. The differences in indications for use do not constitute a new intended use because both devices are a combination of an incubator and a radiant warmer (under regulations 21 CFR 880.5400 & 880.5130), both provide controlled ambient conditions, both are used for the same patient population. The predicate device had already been designed for treating patients of up to 10 kg as this weight limit is specified by the corresponding particular standards IEC 60601-2-19 (FDA recognition number 6-461) and IEC 60601-2-21 (FDA recognition number 6-463). The evidence of conformity with these consensus standards has been provided also in the original submission of predicate device. The 5 kg limit was only included in the intended use of the predicate device to be comparable to its own predicate, the incubator Caleo (K003067).

There were neither hardware nor software changes required on the device to enable the update of the body weight specification.

Change from “premature babies and neonates” to “neonates and infants”: the patient population has been clarified. The terms "neonate" and “infant” for the proposed device have been defined in the indications for use more specifically to align with the identification of pediatric subgroups in FDA Guidance for Industry and Food and Drug Administration Staff: Premarket Assessment of Pediatric Medical Devices.

The following list outlines the technological characteristics that are the same or similar as those of the predicate device (K182859):

- Radiant warmer operation including:
  - Manual mode
  - Skin temperature regulation
  - Kangaroo mode
- Incubator operation including:
  - Humidification
  - Oxygen supply (option)
  - Air temperature regulation
  - Skin temperature regulation
  - Kangaroo mode
- Scale (option)
- Heated, x-ray transparent mattress (option)
- Height adjustment of the device

- Inclination of the mattress tray
- Optical and acoustical alarm system including power supply failure alarm
- Data exchange interfaces

The technological characteristic that differs from the predicate device (K182859) is the integrated battery (option) that supports intrahospital patient transport in incubator operation.

Consequently, the software version 2.01.00, included in the subject device, facilitates functionality for intrahospital patient transport with the battery. Additionally, the software version 2.01.00 contains enhancements of the control software and extended cybersecurity improvements.

Another modification that is subject of this premarket notification is the biocompatibility relevant change of the bed support and the scale. The base material of the bed support and the scale is the same. In the predicate device, the patient bed parts, and the scale were lacquered. The lacquer is now omitted.

The results of the testing, with the comparison of the intended use, proposed indications for use, technology and features of the subject Babyleo TN500 device to the unmodified predicate Babyleo TN500 device (K182859), support a determination of substantial equivalence.

Discussion of Non-clinical Testing

The subject Babyleo TN500 was tested in accordance with applicable standards, guidance, and internal design requirements, including performance testing and functional/operation testing. The results of the non-clinical performance testing support substantial equivalence.

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

Standard Number and Version / Guidance	Title
Electrical, Thermal, and Mechanical Safety	
According to IEC 60601-1 Edition 3.2 2020-08	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Electromagnetic Compatibility	
According to IEC 60601-1-2 Edition 4.1 2020-09	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Standard Number and Version / Guidance	Title
According to IEC TS 60601-4-2 Edition 1.0 2024-03	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
Referring to June 6, 2022, Guidance for Industry and Food and Drug Administration Staff	Electromagnetic Compatibility (EMC) of Medical Devices
Software Documentation	
Developed according to processes conforming to IEC 62304 Edition 1.1 2015-06	Medical device software - Software life cycle processes
According to IEC 81001-5-1 Edition 1.0 2021-12	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle
Referring to June 14, 2023, Guidance for Industry and Food and Drug Administration Staff	Content of Premarket Submissions for Device Software Functions
Referring to August 11, 2023, Guidance for Industry and Food and Drug Administration Staff	Off-The-Shelf Software Use in Medical Devices
Referring to September 27, 2023, Guidance for Industry and Food and Drug Administration Staff	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
Usability/Human Factors	
According to IEC 60601-1-6 Edition 3.2 2020-07	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
According to IEC 62366-1 Edition 1.1 2020-06	Medical devices - Part 1: Application of usability engineering to medical devices
Referring to February 3, 2016, Guidance for Industry and Food and Drug Administration Staff	Applying Human Factors and Usability Engineering to Optimize Medical Device Design
Referring to December 2022, Draft Guidance for Industry and Food and Drug Administration Staff	Content of Human Factors Information in Medical Device Marketing Submissions
Alarm Systems	

Standard Number and Version / Guidance	Title
According to IEC 60601-1-8 Edition 2.2 2020-07	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
Labeling	
According to ISO 15223-1 Fourth edition 2021-07	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
According to ISO 20417 First edition 2021-04	Medical devices - Information to be supplied by the manufacturer
Risk Management	
According to ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices
Biocompatibility	
According to ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
According to ISO 18562-1 Second edition 2024-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
Referring to September 8, 2023, Guidance for Industry and Food and Drug Administration Staff	Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
Processing	
According to ISO 17664-2 First edition 2021-02	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.
Infant Incubators	
According to IEC 60601-2-19 Edition 3.0 2020-09	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators
Infant Radiant Warmers	
According to IEC 60601-2-21 Edition 3.0 2020-09	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
Batteries	

Standard Number and Version / Guidance	Title
According to IEC 62133-2 Edition1.0 2017-02	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

Clinical Performance Testing

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

Conclusion

Based on the indications for use/intended use, technological characteristics, performance/non-clinical testing, and comparison to the predicate device, the subject device is substantially equivalent to the predicate device K182859 and the verification and technical data included in support of substantial equivalence confirms that there are no new questions of safety or effectiveness relating to the modification that is the subject of this premarket notification.

- END -