February 22, 2019

Drägerwerk AG & Co. KGaA
℅ Gale Winarsky
US Agent
Draeger Medical Systems, Inc.
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K182859
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 28, 2019
Received: January 30, 2019

Dear Gale Winarsky:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sapana Patel -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182859

Device Name
Babyleo TN500

Indications for Use *(Describe)*

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).

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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"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 (K182859)

I. SUBMITTER

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Luebeck, Germany

Phone: +49 451 882 0
Fax: +49 451 882 3018

Contact Person: Dr. Bettina Möbius
Submitter's US contact Person: Gale Winarsky
Date prepared: February 14th, 2019

II. DEVICE

Name of Device:	Babyleo TN500
Common or Usual Name:	Incubator and Warmer
Classification Name:	Incubator, neonatal (21 CFR 880.5400)
Regulatory Class:	II
Product code:	FMZ, FMT

III. PREDICATE DEVICE

Babyleo TN500, K162821

IV. DEVICE DESCRIPTION

The device Babyleo TN500 is a medical device used to maintain environmental conditions suitable for preterm babies and neonates. The important features are temperature and humidity. The operational principle is a combination of a neonatal incubator and an open warmer.
Babyleo TN500 can be operated in closed care therapy as an incubator according to IEC60601-2-19 or in open care therapy as a warmer according to IEC60601-2-21.
Additionally, an optional x-ray translucent heated mattress is intended to provide sensible heat to the preterm babies and neonates.
The device consists of the following components: Incubator (=bassinet) with a convection heater and closed humidification system for the patient, trolley, radiant warmer, display, mattress, x-ray tray and height adjustment.

Optional components are scale, heated mattress, drawer, oxygen regulation with cylinder holder and Auto Thermo package and Developmental Care package.
The subject of this submission is the addition of the optional Touch time function, which can be activated in order to stabilize the thermal environment in the patient compartment when the hand ports are opened. It supports users during routine tasks (e.g. changing diapers, washing the baby, checking sensors). Additionally, the scale resolution is changed from 5g to 10g.

V. INDICATIONS FOR USE

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).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The primary technological characteristics of the Babyleo TN500 remain unchanged. The medical device is an incubator and an open warmer. The modification adds an optional Touch Time feature, which increases air circulation and disables the audio signals of certain alarms for a maximum of 20 minutes. The change in the scale resolution from 5g to 10g does not affect the functionality of the device.

VII. PERFORMANCE DATA

The performance specifications of Babyleo TN500 remain unchanged. The results of the risk analysis and verification testing performed for the Touch time feature indicate no new issues related to the safety and effectiveness of the modified device. Testing was performed according to applicable Standards IEC 60601-1; 60601-1-2; 60601-2-19; and 60601-2-21.

Software Verification and Validation Testing
Verification and validation testing were conducted in conformance to the FDA recognized standards. Performance data only related to the Touch time feature has been tested and evaluated.

Risk Analysis
An analysis of the risk for the modification Touch time for the Babyleo TN500 was carried out according to ISO 14971. Possible risks were identified which result from the modification Touch time. Based on the risk identification, Risk Control Measures for the Touch time feature were defined and Verification and Validation activities were carried out in order to ensure risk acceptability criteria have been met and the risks have been mitigated.

VIII. CONCLUSIONS

The intended use of Babyleo TN500 has not been changed as a result of these modifications. The comparison with the predicate device and the results from a risk analysis and verification testing of the modified Babyleo TN500 demonstrate that it is as safe and effective as the previously cleared predicate in K162821.

	Babyleo TN500	Babyleo TN500 Special 510(k)
Status	K162821	
Manufacturer	Drägerwerk AG & Co. KGaA	Identical
Classification Name / **Product code**	Incubator, neonatal / Warmer, Infant Radiant FMZ/FMT	Identical
510(k)	K162821	
Regulation Number:	21 CFR 880.5400	Identical
Class:	II	Identical
Standards	60601-1; 60601-1-2; 60601-2-19; 60601-2-21	Identical
Indications for use	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).	Identical
Operating noise		
Operating noise volume in patient compartment	Typically 40 dB(A) (Measured without oxygen application)	Identical

	Babyleo TN500	Babyleo TN500 Special 510(k)
Alarm Volume	50 to 70 dB(A) (according to IEC 60601-2-19 and IEC 60601-2-21)	Identical
Power failure alarm	Yes (65 dB(A), 10 min)	Identical
Principles of operation		
General	Radiant Warmer and Neonatal Incubator	Identical
Warmer operation		
Warmer	Radiant Warmer	Identical
Maximum Irradiance of Warmer	32 mW/cm2 (at 100% power); 18 mW/cm2 (at 60% poser) 10 mW/cm2 (at 30% Power)	Identical
Incubator operation		
Heater	Convective heater	Identical
Warm up time	15 to 20 min	Identical
Humidification principle	Boiling of Aquadest (destilled water)	Identical
Flow velocity over mattress surface	10 cm/s (3.94 in/s) (at 36°C)	Identical
Maximum Carbon Dioxide (CO2) concentration in the incubator measured in accordance with IEC 60601-2-19	<0.5 Vol%	Identical
Electrical Description		

	Babyleo TN500	Babyleo TN500 Special 510(k)
Power supply	100 V to 240 V, 50/60 Hz	Identical
Maximum current / power consumption	10A / 1000W	Identical
Electrical safety	according to IEC 60601-1	Identical
Gas supply (option)		
O2 operating pressure	270 to 600 kPa	Identical
Measured value display		
Radiant Warmer		
Setting range	Off, 10 % to 100 %	Identical
Prewarm Mode	Yes	Identical
Air temperature regulation		
Measurement regulation	13 to 45 °C (55.4 to 113 °F)	Identical
Measurement uncertainty	± 0.8°C (1.44 °F)	Identical
Air Mode temperature setting range	20 to 39 °C (68 to 102.2 °F) in 0.1 ° inc.	Identical
Air Mode override	<28 °C (82.4 °F), after confirmation >37 °C (98.6 °F), after confirmation	Identical

	Babyleo TN500	Babyleo TN500 Special 510(k)
Skin Temperature regulation		
Measurement range	13 to 43 °C (55.4 to 109.4 °F)	Identical
Temperature Sensor for Skin	Thermo Trace (Dräger)	Identical
Measurement uncertainty sensors	± 0.1°C (0.18 °F)	Identical
Measurement uncertainty entire system	± 0.3°C (0.54 °F)	Identical
Skin temperature Mode setting range	34 to 38 °C (93.2 to 100.4 °F) in 0.1 °C	Identical
Skin temperature Mode override	>37 °C (98.6 °F), after confirmation	Identical
Heated mattress (Option)		
Setting range	Off, 35°C to 39°C, AUTO	Identical
Oxygen regulation (Option)		
Measurement range	Normal range: 18 to 65 Vol % Extended range: 66 to 99 Vol%	Identical
Measurement uncertainty	± 2.5 Vol% (+ 2.5 % of measured value)	Identical
Setting range	21 to 65 Vol% (>40 Vol%, after confirmation)	Identical
O2 rise time from 21 to 65 Vol%	<10 min	Identical

	Babyleo TN500	Babyleo TN500 Special 510(k)
Oxygen Cylinder Holder	Yes	Identical
Humidity System Description		
Measurement range	Normal range: 30 to 99 % r. H. Extended range: 10 to 29 % r. H.	Identical
Measurement uncertainty	±10 %	Identical
Setting Range	Off, 30 to 99 % r. H. in steps of 1 %, AUTO	Identical
Noise and light measurement (Developmental care package Option)	Yes	Identical
Noise Measurement range	40 to 90 dB(A)	Identical
Light Measurement range	3 to 999 Lux (1 to 93 fc)	Identical
AutoThermo package (Option)	Yes	Identical
Data exchange and interfaces	Serial Port (COM, RS232), USB (USB 1.1 or USB 2.0); Service port (RJ45 / LAN)	Identical
Physical Description		
Weight (without options and accessories)	<140 kg	Identical
Width & Depth	690 mm x 1154 mm (27.17 in x 45.43 in)	Identical
Height (with hood closed)	1850 mm to 2250 mm (72.83 in to 88.58 in)	Identical

	Babyleo TN500	Babyleo TN500 Special 510(k)
	(height adjustment range: 400 mm)	
Height of the mattress Surface	700 to 1100 mm (27.56 in to 43.31 in)	Identical
Mattress	450 mm x 690 mm (17.72 in x 27.17 in)	Identical
Material (no implants)		
Material used for indirect patient contact	Metal (e.g Aluminium) Synthetic material (e.g. TPE)	Identical
Material used for direct patient contact	Textile (Vowalon Medilind)	Identical
Biocompatibility	according to ISO 10993	Identical
Sterilization	N/A; non sterile	Identical
Scale Description		
Range	200 g to 10 kg	Identical
Resolution	5 g (OIML)) or 1 g (standard version)	10 g (OIML) or 1 g (1 oz)
Integrated X-ray cassette / tray	Yes	Identical
Drawer (Option)	Yes	Identical
Bed-tilt mechanism (Trendelenburg)	Continuous up to 13°	Identical

	Babyleo TN500	Babyleo TN500 Special 510(k)
Environmental Description during operation		
Ambient operating temperature	20 to 35 °C (68 to 95°F)	Identical
Operating barometric range	620 to 1100 hPa (9.0 to 16.0 psi)	Identical
Humidity operating range	20 to 95 %, noncondensing	Identical
Environmental Description during storage	Temperature - 20 to 60 °C (to 4 to 140 °F) Ambient pressure 500 to 1100 hPa (7.3 to 16.0 psi) Relative humidity 10 to 95 %, non-condensing	Identical
Touch Time Option	N/A	The optional Touch time function can be activated in order to stabilize the thermal environment in the patient compartment when the hand ports are opened.