DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 23, 2017

Draegerwerk AG & Co. KGaA
℅ Ms. Beth Zis
Director, Regulatory Affairs
Draeger Medical Systems, Inc.
6 Tech Drive
Andover, Massachusetts 01810

Re: K162821
Trade/Device Name: Babyleo TN500
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: Class II
Product Code: FMZ, FMT
Dated: May 24, 2017
Received: May 30, 2017

Dear Ms. Beth Zis:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

James P. Bertram -S

for

Lori A. Wiggins, MPT, CLT
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162821

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.

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510(k) Summary **K162821**

Applicants / Manufacturer Name and Address:

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Date submission was prepared:

06/05/2017

Device Name:

Device Trade Name:	Babyleo TN500
Common / Usual Name:	Incubator and Warmer
Classification Name	Incubator, neonatal 21 CFR 880.5400
Regulatory Class:	II
Product Code:	FMZ, FMT

Legally Marketed Devices to which Substantial Equivalence is claimed:
Legally Marketed Predicate Device:
K010222, Ohmeda Medical Giraffe Incubator
Reference Devices:
K003067, CALEO
K971198, Babytherm 8004/8010

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.

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)

Substantial Equivalence Comparison:

	Babyleo TN500	Omnibed (Giraffe)	Caleo	Babytherm 8004/8010	Comments
Status	new device	predicate device	reference device	reference device	
Manufacturer	Drägerwerk AG & Co. KGaA	Ohmeda Medical, a Division of Datex-Ohmeda,Inc. A GE Company	Drägerwerk AG & Co. KGaA	Drägerwerk AG & Co. KGaA	
Classification Name / Product code	Incubator, neonatal / FMZ	Incubator, neonatal / FMZ	Incubator, neonatal / FMZ	Infant Radiant Warmer / FMT	Same
510(k)	K162821	K010222;	K003067	K971198	
Regulation Number:	21 CFR 880.5400	21 CFR 880.5400	21 CFR 880.5400	21 CFR 880.5130	Same
Class:	II	II	II	II	Same
Standards	60601-1; 60601-1-2; 60601-2-19; 60601-2-21	60601-1; 60601-1-2; 60601-2-19; 60601-2-21	60601-1; 60601-1-2; 60601-2-19	60601-1; 60601-1-2; 60601-2-21	Same
Indications for use	The 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	The OmniBed is a combination of an infant incubator (“incubator”) and an infant radiant warmer(“warmer”). Incubators and warmers provide heat in a controlled manner to neonates who are unable to thermoregulate based on their own physiology. Incubators provide an enclosed,	Caleo® is an infant incubator system for premature babies and sick infants up to a body weight of 5 kg (11 lbs) or a body length of 55 cm (22 inches), providing a controlled environment of warmth, humidity, and elevated O2 concentration in the patient area. The total body weight when	Babytherm 8004/8010 is an open care infant warmer system for warming premature babies, neonates and infants with a body weight of up to 8 kg (17.6 lbs). The device is intended for use in delivery rooms, operating rooms, maternity and obstetric units, neonatal and pediatric wards,	The indications for use of the Babyleo TN500 and the predicate device are equivalent. The differences do not raise questions about the safety or effectiveness for the subject device.

	Babyleo TN500	Omnibed (Giraffe)	Caleo	Babytherm 8004/8010	Comments
	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)	temperature controlled environment and warmers provide infrared heat in an open environment. They may also be used for short periods of time to facilitate the neonate's transition from the uterus to the external environment.	treating twins is limited to 5 kg (11 lbs). Caleo is intended for use in clinical environments where premature babies or infants are treated who require a controlled climatic environment.	neonatal and pediatric intensive care units.	
Operating noise					
Operating noise volume in patient compartment	Typically 40 dB(A) (Measured without oxygen application)	<49 dB(A)	47 ±2 dB(A)	no closed patient compartment	Similar

	Babyleo TN500	Omnibed (Giraffe)	Caleo	Babytherm 8004/8010	Comments
Alarm Volume	50 to 70 dB(A) (according to IEC 60601-2-19 and IEC 60601-2-21)	according to IEC 60601-2-19	according to IEC 60601-2-19	Not provided	Similar
Power failure alarm	Yes (65 dB(A), 10 min)	Yes	Yes	Yes	Same
Principles of operation					
General	Radiant Warmer and Neonatal Incubator	Radiant Warmer and Neonatal Incubator	Neonatal Incubator	Radiant Warmer	Same
Warmer operation					
Warmer	Radiant Warmer	Radiant Warmer	NA (Incubator only)	Radiant Warmer	Same
Maximum Irradiance of Warmer	32 mW/cm2 (at 100% power); 18 mW/cm2 (at 60% poser) 10 mW/cm2 (at 30% Power)	Not provided	NA (Incubator only)	30 mW/cm2 (heat level 10); 10mW/cm2 (heat level 3)	Same
Incubator operation					
Heater	Convective heater	Convective heater	Convective heater	NA (Radiant Warmer only)	Same
Warm up time	15 to 20 min	< 50 min	20 min	NA (warmer only)	Similar
Humidification principle	Boiling of Aquadest (destilled water)	Drawover Evaporator	Boiling of Aquadest	NA (warmer only)	Similar
Flow velocity over matress surface	10 cm/s (3.94 in/s) (at 36°C)	<10 cm/s	< 8 cm/s	NA (warmer only)	Same
Maximum Carbon Dioxide (CO_2) concentration in the incubator measured in accordance with IEC 60601-2-19	<0.5 Vol%	0.2 %	<0.5 Vol%	max 0.5 Vol% (with bed canopy)	Same

	Babyleo TN500	Omnibed (Giraffe)	Caleo	Babytherm 8004/8010	Comments
Electrical Description					
Power supply	100 V to 240 V, 50/60 Hz	100V, 115V, 220V, 230V, 240V, 50/60 Hz	100V, 110V, 120 V, 127V, 220V to 240V; 50 Hz / 60 Hz	100V, 110 - 127 V; 220 - 240 V	Same
Maximum current / power consumption	10A / 1000W	not provided	8.7A / 732W	15A / 1750 W	Similar
Electrical safety	according to IEC 60601-1	according to IEC 60601-1	according to IEC 60601-1	according to IEC 60601-1	Same
Gas supply (option)					
O2 operating pressure	270 to 600 kPa	not provided	300 and 600 kPa (43.5 and 87 psi).	NA (warmer only)	Similar
Measured value display					
Radiant Warmer					
Setting range	Off, 10 % to 100 %	0 to100 % in 5% INC	NA (Incubator only)	not provided	Same
Prewarm Mode	Yes	Yes	NA (Incubator only)	Yes	Same
Air temperature regulation					
Measurement regulation	13 to 45 °C (55.4 to 113 °F)	Not provided	13 to 42 °C (55.4 °F to 107.6 °F)	NA (warmer only)	Similar
Measurement uncertainty	± 0.8°C (1.44 °F)	Not provided	± 0.8°C (1.44 °F)	NA (warmer only)	Same
Air Mode temperature setting range	20 to 39 °C (68 to 102.2 °F) in 0.1 ° inc.	20 to 39 °C in 0.1 ° inc.	20 to 39 °C (68 to 102.2 °F)	NA (warmer only)	Same
Air Mode override	<28 °C (82.4 °F), after confirmation >37 °C (98.6 °F), after confirmation	Not provided	<28 °C (82.4 °F), after confirmation >37 °C (98.6 °F), after confirmation	NA (warmer only)	Same

	Babyleo TN500	Omnibed (Giraffe)	Caleo	Babytherm 8004/8010	Comments
Skin Temperature regulation					
Measurement range	13 to 43 °C (55.4 to 109.4 °F)	Not provided	NA (Incubator only)	15 °C to 42 °C	Similar
Temperature Sensor for Skin	Thermo Trace (Dräger)	Not provided	Thermo Trace (Dräger)	Thermo Trace (Dräger)	Same
Measurement uncertainty sensors	± 0.1°C (0.18 °F)	Not provided	± 0.1°C (0.18 °F)	± 0.1°C (0.18 °F)	Same
Measurement uncertainty entire system	± 0.3°C (0.54 °F)	± 0.3°C (0.54 °F)	± 0.3°C (0.54 °F)	± 0.3°C (0.54 °F)	Same
Skin temperature Mode setting range	34 to 38 °C (93.2 to 100.4 °F) in 0.1 °C	35 to 37.5 °C in 0.1 °C	34 to 38 °C (93.2 to 100.4 °F)	not provided	Same
Skin temperature Mode override	>37 °C (98.6 °F), after confirmation	Not provided	>37 °C (98.6 °F), after confirmation	not provided	Same
Heated mattress (Option)					
Setting range	Off, 35°C to 39°C, AUTO	Not provided	NA	Off, 30°C to 38.5°C	Similar
Oxygen regulation (Option)					
measurement range	Normal range: 18 to 65 Vol % Extended range: 66 to 99 Vol%	Not provided	Normal range: 18 to 65 Vol % Extended range: 66 to 99 Vol%	NA (warmer only)	Same
Measurement uncertainty	± 2.5 Vol% (+ 2.5 % of measured value)	5%	± 3 Vol%	NA (warmer only)	Same
Setting range	21 to 65 Vol% (>40 Vol%, after confirmation)	21 to 65%	21 to 75 vol%	NA (warmer only)	Same
O2 rise time from 21 to 65 Vol%	<10 min	10 minutes from 21% to 5% below set point	Not provided	NA (warmer only)	Same
Oxygen Cylinder Holder	Yes	Yes	Yes	NA (warmer only)	Same

	Babyleo TN500	Omnibed (Giraffe)	Caleo	Babytherm 8004/8010	Comments
Humidity System Description					
Measurement range	Normal range: 30 to 99 % r. H. Extended range: 10 to 29 % r. H.	up to 85%	set point range: 30 to 99 % r. H. measure range: 10 to 99 % r. H.	NA (warmer only)	Same
Measurement uncertainty	±10 %	±10 %	±10 %	NA (warmer only)	Same
Setting Range	Off, 30 to 99 % r. H. in steps of 1 %, AUTO	30 to 95% in 5% increments	Off, 30 to 99 % r. H. in steps of 1 %, AUTO	NA (warmer only)	Same
Noise and light measurement (Developmental care package Option)	Yes	No	No	No	Different
Noise Measurement range	40 to 90 dB(A)	not available	not available	not available	Different
Light Measurement range	3 to 999 Lux (1 to 93 fc)	not available	not available	not available	Different
AutoThermo package (Option)	Yes	No	No	No	Different
Data exchange and interfaces	Serial Port (COM, RS232), USB (USB 1.1 or USB 2.0); Service port (RJ45 / LAN)	ThermaLink Serial data interface (RS232);	Serial Port (COM, RS232), Service port (RJ45 / LAN)	Serial Port (COM, RS232), Service port (RJ45 / LAN)	Same
Physical Description					
Weight (without options and accessories)	<140 kg	138 kg	130 kg (max. 230 kg)	133 kg	Similar
Width & Depth	690 mm x 1154 mm (27.17 in x 45.43 in)	690 mm x 1120 mm	687 mm x 1167 mm	750 mm x 1315 mm	Similar
Height (with hood closed)	1850 mm to 2250 mm (72.83 in to 88.58 in) (height adjustment range: 400 mm)	1470 mm to 1770 mm (height adjustment range: 300 mm)	1220 mm to 1520 mm	1896 mm to 2210 mm	Similar

	Babyleo TN500	Omnibed (Giraffe)	Caleo	Babytherm 8004/8010	Comments
Height of the mattress surface	700 to 1100 mm (27.56 in to 43.31 in)	Not provided	800 mm to 1100 mm	885 mm to 1180 mm	Similar
Mattress	450 mm x 690 mm (17.72 in x 27.17 in)	Not provided	500 mm x 645 mm	490 mm x 750 mm	Similar
Material (no implants)					
Material used for indirect patient contact	Metal (e.g Aluminium) Synthetic material (e.g. TPE)	Unknown	Metal (e.g Aluminium) Synthetic material (e.g. TPE)	Metal (e.g Aluminium) Synthetic material (e.g. TPE)	Similar
Material used for direct patient contact	Textile (Vowalon Medilind)	Unknown	Textile (Polyurethane)	Textile (Polyurethane)	Similar
Biocompatibility	according to ISO 10993	according to ISO 10993	according to ISO 10993	according to ISO 10993	Same
Sterilization	N/A; non sterile	N/A; non sterile	N/A; non sterile	N/A; non sterile	Same
Scale Description					
Range	200 g to 10 kg	300 g to 8 kg	250 g to 10 kg	250 g to 8 kg	Similar
Resolution	5 g (OIML)) or 1 g (standard version)	10 g or 5 g	1 g or 5 g (OIML)	1 g or 10 g (OIML)	Similar
Integrated X-ray cassette / tray	Yes	Yes	Yes	Yes	Same
Drawer (Option)	Yes	Yes	Yes	Yes	Same
Bed-tilt mechanism (Trendelenburg)	Continuous up to 13°	12° mechnical tilt	Up to 13° (± tilt angle)	15 to 20°	Similar
Enviromental Description during operation					
Ambient operating temperature	20 to 35 °C (68 to 95°F)	20 to 30 °C	20 to 25 °C	15 to 35 °C	Similar
Operating barometric range	620 to 1100 hPa (9.0 to 16.0 psi)	Not provided	600 to 1060 hPa	900 hPa to 1060 hPa	Similar

	Babyleo TN500	**Omnibed (Giraffe)**	**Caleo**	**Babytherm 8004/8010**	**Comments**
Humidity operating range	20 to 95 %, non-condensing	10 to 95% non condensating	10 to 95%, non.-condensating	0 to 75 %, no condensation	Similar
Enviromental 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	Temperature - 25 to 60°C Humidity 0 to 95% Non-condensing relative humidity Pressure 50 to 106 kPa	Temperature - 20 to 60 °C (- 4 to 140 °F) Ambient pressure 210 - 1060 hPa Relative humidity 10 - 95 %, non-condensing	Temperature - 20 to 60 °C (- 4 to 140 °F) Ambient pressure 700 - 1060 hPa Relative humidity 0 - 90 %, non-condensing	Similar

The Omnibed (Giraffe) is the predicate device for Babyleo TN500. Both devices are operated as a neonatal incubator and as an infant radiant warmer.
The Caleo is a reference device for Babyleo TN500. Both devices are operated as a neonatal incubator.
The Babytherm 8004/8010 is a reference device for Babyleo TN500. Both devices are operated as an infant radiant warmer.

Differences:
The noise and light measurement and audio stimulation are new optional features to enable further developmental care activities in the NICU.
The Auto Thermo Package is a new optional feature containing tolerate cooling, warm up and weaning to ease processes in the NICU.
The indications for use of the Babyleo TN500 and the predicate device are equivalent.
The differences do not raise questions about the safety or effectiveness for the subject device.

Summary of Testing
The following performance data were provided:

Electrical safety and electromagnetic compatibility (EMC), incl. performance testing
Electrical safety and EMC testing were conducted on the Babyleo TN500. The device complies with the IEC 60601-1, IEC 60601-2-19, IEC 60601-2-21 and IEC 60601-2-35 standards for safety and performance and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."2005. The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Biocompatibility testing
The biocompatibility evaluation for the Babyleo TN500 was conducted in accordance with the FDA guidance on Biocompatibility on the International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,', and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Integral Test for volatile organic compounds
- Photogenic bacteria test
- Emission of particles
- Material characterization according to ISO 10993-18
- Toxicological Evaluation according to ISO 10993-17
- Cytotoxicity
- Irritation
- Sensitization

Human Factor
The usability evaluation for the Babyleo TN500 device was conducted in accordance with the FDA guidance: Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff, 2016.

Reprocessing
The reprocessing validation for the Babyleo TN500 device was conducted in accordance with the FDA guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling; Guidance for Industry and Food and Drug Administration Staff, 2015

Animal Study
No animal study have been conducted.

Clinical Studies
No Clinical testing has been done.

Conclusion:
Based on device comparison information and non-clinical bench testing data, the proposed device is substantially equivalent to legally marketed predicate device K010222.