May 16, 2023

Draegerwerk AG & CO KGaA
Nataliia Semenova
Regulatory Affairs Manager
53/55 Moislinger Allee
Luebeck, Schlewsig-Holstein 23542
Germany

Re: K222207
Trade/Device Name: Babylog VN800, Babylog VN600
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: April 17, 2023
Received: April 17, 2023

Dear Nataliia Semenova:

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,

Ting Song -S

For
James J. Lee, Ph.D.
Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*
K222207

Device Name
Babylog VN800 / Babylog VN600

Indications for Use *(Describe)*
The Babylog intensive care Ventilator (Babylog VN800 / Babylog VN600) is intended for the ventilation of neonates with a body weight of0.4 kg (0.88 lb) to 10 kg (22 lb) and for pediatric patients with an IBW of 5.2 kg (11.5 lb) to 20.1 kg (44.3 lb).
This device provides mandatory pressure-controlled ventilation modes, ventilation modes for supporting spontaneous breathing, and ventilation monitoring.

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) Premarket Notification Summary

Submitter:
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Establishment's registration number: 9611500

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Date prepared: 16 May 2023

Device Name:

Common name:	Ventilator
Trade Name:	Babylog VN800, Babylog VN600
Classification Name:	Ventilator, Continuous, Facility Use
Regulation Number:	21 CFR §868.5895
Product Code:	CBK
Class:	II

Predicate Device: Infinity Acute Care System Workstation Neonatal Care, K093632

Drägerwerk AG & Co. KGaA is submitting a traditional 510(k) premarket notification for a new device, Babylog VN800 / Babylog VN600.

Device Description

The intensive care ventilators Babylog VN800 and Babylog VN600 were developed and are manufactured by Dräger in Lübeck, Germany.

Babylog VN800 and Babylog VN600 are specified for the ventilation of pediatric patients and neonates. These devices provide mandatory ventilation modes and ventilation modes for supporting spontaneous breathing as well as ventilation monitoring.

Babylog VN800 and Babylog VN600 are available in different device variants and can additionally be upgraded by software and hardware options as well as attachable accessories.

Babylog VN800 and Babylog VN600 are available with a basic device configuration that comprises the following:

– Trolley with four castors and brakes

– Display unit (graphical user interface)

– Ventilation unit

The changes have been made in the device design including functional integration of the Infinity series C cockpit into the device by changing “PC based Cockpit technology” to an “Embedded Control Display (ECD) technology” including a visually updated (color) in the graphical user interface. The hardware complexity has been reduced. In addition, a Gas supply Unit has been added as well as the Power supply Unit as an option. The device software and firmware have been redesigned. The functionality and features of Babylog VN800 / VN600 are identical to the predicate device.

Intended Use / Indications for Use

The Babylog intensive care ventilator (Babylog VN800 / Babylog VN600) is intended for the ventilation of neonates with a body weight of 0.4 kg (0.88 lb) to 10 kg (22 lb) and for pediatric patients with an IBW of 5.2 kg (11.5 lb) to 20.1 kg (44.3 lb).

This device provides mandatory pressure-controlled ventilation modes, ventilation modes for supporting spontaneous breathing, and ventilation monitoring.

List of Consensus Standards

Standard Number and Version	Title
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	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 Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8 Edition 2.1 2012-11	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
ISO 80601-2-12 First edition 2011-04-15	Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators [Including: Technical Corrigendum 1 (2011)]
ISO 80601-2-55 Second edition 2018-02	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
IEC 62366-1 Edition 1.0 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices

ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 18562-1 First edition 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
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
IEC 62133-1 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 1: Nickel systems
/TR 60601-4-2 Edition 1.0 2016-05	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Comparison to Predicate

Topic	*Proposed device* *BABYLOG VN800, BABYLOG VN600*	*Predicate device* *Infinity Acute Care System Workstation Neonatal Care*	*Comments*
Device Trade Name	Babylog VN800 Babylog VN600	Infinity Acute Care System Workstation Neonatal Care	–
Manufacturer	Drägerwerk AG & Co. KGaA	Drägerwerk AG & Co. KGaA	Same
510(k) number	K222207	K093632	–
Regulation number - Classification description	868.5895 - Continuous Ventilator	868.5895 - Continuous Ventilator	Same
Regulatory class	Class II	Class II	Same
Product code	CBK	CBK	Same
Patient population	• Pediatric • Neonate	• Pediatric • Neonate	Same

Topic	*Proposed device* *BABYLOG VN800, BABYLOG VN600*	*Predicate device* *Infinity Acute Care System Workstation Neonatal Care*	*Comments*
Intended Use / Indications for Use	The Babylog intensive care ventilator (Babylog VN800 / Babylog VN600) is intended for the ventilation of neonates with a body weight of 0.4 kg (0.88 lb) to 10 kg (22 lb) and for pediatric patients with an IBW of 5.2 kg (11.5 lb) to 20.1 kg (44.3 lb). This device provides mandatory pressure-controlled ventilation modes, ventilation modes for supporting spontaneous breathing, and ventilation monitoring.	The Infinity Acute Care System Workstations Neonatal Care consists of monitoring and control displays and additional therapy. They are intended to be used as integrated, networked, and configurable Workstations to provide specific therapy in neonatal intensive care. The Infinity Acute Care System Workstations Neonatal Care are intended to be used by qualified and trained medical personnel. The Infinity CSeries Medical Cockpits, consisting of the C500 and and the C700, are monitoring and control displays for the Infinity Acute Care System (IACS). Medical Cockpits are intended to be used to monitor waveforms, parameter information, and alarms as well as to control settings. The Infinity CSeries Medical Cockpits are intended to be used in environments where patient care is provided by trained healthcare Professionals. **The Babylog VN500 Ventilation unit of the Infinity Care System is intended for the ventilation of neonatal patients from 0.4 kg (0.88 lbs) up to 10 kg (22 lbs) and pediatric patients from 5 kg (11 lbs) up to 20 kg (44 lbs) bodyweight. Babylog VN500 offers mandatory ventilation modes for spontaneous breathing support and airway monitoring. The Babylog VN500 ventilation unit is intended for use in different medical care areas.** Babylog VN500 is intended for stationary use in hospitals and medical rooms or for patient transportation within the hospital.	Similar

Topic	*Proposed device* *BABYLOG VN800, BABYLOG VN600*	*Predicate device* *Infinity Acute Care System Workstation Neonatal Care*	*Comments*
Intended user	The operating organization must ensure the following: • Every user group has the required qualifications (e.g., has undergone specialist training or acquired specialist knowledge through experience). • Every user group has been trained to perform the task. Clinical users This user group operates the product in accordance with the intended use. Users have medical specialist knowledge in the field of ventilation. Users have knowledge of device monitoring and ventilation care.	The Infinity Acute Care System Workstations Neonatal Care are intended to be used by qualified and trained medical personnel. The Infinity CSeries Medical Cockpits are intended to be used in environments where patient care is provided by trained healthcare Professionals.	Similar
Environment of use	The device is intended for stationary use in hospitals and medical rooms or for intrahospital patient transport. Do not use the device in the following environments of use: – Hyperbaric chambers – Magnetic resonance imaging – Together with flammable gases or flammable solutions that can mix with air, oxygen, or nitrous oxide – Areas with danger of explosion – Areas with combustible and highly flammable substances – Rooms with insufficient ventilation Do not operate the device with helium or helium mixtures.	Babylog VN500 is intended for stationary use in hospitals and medical rooms or for patient transportation within the hospital. Do not use the device in the following environments: – In hyperbaric chambers – For magnetic resonance imaging (MRI, NMR, NMI) – In conjunction with flammable gases or flammable solutions that can mix with air, oxygen or nitrous oxide – In areas of explosion hazard – In areas with combustible or explosive substances – In rooms without sufficient ventilation Do not operate the device with helium or helium mixtures.	Similar

Topic	*Proposed device* *BABYLOG VN800, BABYLOG VN600*	*Predicate device* *Infinity Acute Care System Workstation Neonatal Care*	*Comments*
Gas supply	Central gas supply	Central gas supply	Same
	Gas cylinders • Transport supply unit (optional) • Gas cylinder holder (optional)	Gas cylinders • Transport supply unit (optional) • Gas cylinder holder (optional)	Same
	Gas supply unit GS500 (optional)	-	Different
Gas dosage, mixing and delivery	Dosage of Air/O_2 in mixing chamber	Dosage of Air/O_2 in mixing chamber	Same
	Inspiratory valve	Inspiratory valve	Same
	Expiratory valve	Expiratory valve	Same
	Pneumatic nebulizer (optional, part of “Nebulizer” option)	Pneumatic nebulizer (optional, part of “Medication nebulization” option)	Same
Pressure and volume monitoring	Inspiratory and expiratory pressure	Inspiratory and expiratory pressure	Same
	Inspiratory flow/volume	Inspiratory flow/volume	Same
	Proximal flow/volume	Proximal flow/volume	Same
	2 ambient pressure sensors	1 ambient pressure sensor and user setting altitude	Similar
Oxygen monitoring	Paramagnetic side-stream sensor	Paramagnetic side-stream sensor	Same
	Flow balancing of Air and O_2	Flow balancing of Air and O_2	Same
Carbon dioxide monitoring	Main-stream sensor using infrared absorption spectroscopy (optional, part of “CO2 monitoring” option) • part no.6871950 MCable - Mainstream CO2 • part no. 6873570 CO2 mainstream sensor	Main-stream sensor using infrared absorption spectroscopy (optional, part of “CO2 monitoring” option) • part no.6871950 MCable - Mainstream CO2	Different optional component 6873570 (K221118) was introduced.
Batteries	Internal battery (NiMH)	Internal battery (NiMH)	Same

Topic	*Proposed device* *BABYLOG VN800, BABYLOG VN600*	*Predicate device* *Infinity Acute Care System Workstation Neonatal Care*	*Comments*
	Power supply unit PS500 (optional) • part no. 8418950 lead-acid • part no. 8422900 lithium iron phosphate (LFP)	-	Different
User interface	TFT LCD capacitive touchscreen display • Babylog VN800: 18.5 in • Babylog VN600: 15.6 in	TFT LCD resistive touchscreen display • IACS Medical cockpit C500: 17 in	Similar
	Rotary knob for selecting, adjusting and confirming	Rotary knob for selecting, adjusting and confirming	Same
	Power supply indicators	Power supply indicators	Same
	On/off key	On/off key	Same
	Operation display	Operation display	Same
	Bed coupling (optional)	-	Different
User interface, screen displays	• Waveforms • Graphical trends • Tabular trends • Loops • Alarm logbook • Logbook • Numeric parameters • Lists of measured values and set values • User-specific list for measured values and set values • Smart Pulmonary View (optional)	• Curves • Graphical trends • Numeric trends • Loops • Alarm history • Logbook • Numeric parameters • Preconfigured lists of measured values and set values • Customized lists for measured values and set values • Smart Pulmonary View (optional)	Same
General monitoring, alarm principles	Optical and acoustical alarm indication	Optical and acoustical alarm indication	Same
	Alarm silence key	Alarm silence key	Same
	High, medium and low alarm priorities	High, medium and low alarm priorities	Same

Topic	*Proposed device* *BABYLOG VN800, BABYLOG VN600*	*Predicate device* *Infinity Acute Care System Workstation Neonatal Care*	*Comments*
	Downgrading and resetting of defined alarms	Downgrading and resetting of defined alarms	Same
	Alarm logbook	Alarm history	Same
	Nurse call (optional)	Nurse call (optional)	Same
Device monitoring	User-initiated system test	User-initiated system test	Same
	Gas supply	Gas supply	Same
	Power supply	Power supply	Same
	Device temperature	Device temperature	Same
	Mutual Processor Monitoring	Mutual Processor Monitoring	Same
	Connection to display unit	Connection to display unit	Same
Communication protocols	MEDIBUS	MEDIBUS	Same
	MEDIBUS.X	-	Different
	MED.X.Comp	-	Different
Therapy types	Invasive ventilation (Tube)	Invasive ventilation (Tube)	Same
	Non-invasive ventilation (NIV) (optional)	Non-invasive ventilation (NIV) (optional)	Same
	O2 Therapy	O2 Therapy	Same
Type of patient interface	Invasive ventilation (Tube): – Endotracheal tube (for pediatric patients and neonates) – Tracheostomy cannula (for pediatric patients)	Invasive ventilation (Tube): – Endotracheal tube (for pediatric patients and neonates) – Tracheostomy cannula (for pediatric patients)	Same
	Non-invasive ventilation (NIV) (optional): – NIV mask (for pediatric patients and neonates) – Prongs (for pediatric patients and neonates)	Non-invasive ventilation (NIV) (optional): – NIV mask (for pediatric patients and neonates) – Prongs (for pediatric patients and neonates)	Same

Topic	*Proposed device* *BABYLOG VN800, BABYLOG VN600*	*Predicate device* *Infinity Acute Care System Workstation Neonatal Care*	*Comments*
	O2 Therapy: – Nasal cannula (for pediatric patients and neonates)	O2 Therapy: – Nasal cannula (for pediatric patients and neonates) – Oxygen mask (for pediatric patients and neonates)	Same
Ventilation modes	Pressure Control - Synchronized Intermittent Mandatory Ventilation, PC-SIMV	Pressure Control - Synchronized Intermittent Mandatory Ventilation, PC-SIMV	Same
	Pressure Control - Assist Control, PC-AC	Pressure Control - Assist Control, PC-AC	Same
	Pressure Control - Controlled Mandatory Ventilation, PC-CMV	Pressure Control - Continuous Mandatory Ventilation, PC-CMV	Same
	Pressure Control - Airway Pressure Release Ventilation, PC-APRV (optional)	Pressure Control - Airway Pressure Release Ventilation, PC-APRV (optional)	Same
	Pressure Control - Pressure Support Ventilation, PC-PSV	Pressure Control - Pressure Support Ventilation, PC-PSV	Same
	Pressure Control - Mandatory Minute Ventilation, PC-MMV (optional, part of “Volume ventilation” option)	Pressure Control - Mandatory Minute Volume Ventilation, PC-MMV (optional, part of “Volume ventilation” option)	Same
	Spontaneous - Continuous Positive Airway Pressure, Pressure Support, SPN-CPAP/PS	Spontaneous - Continuous Positive Airway Pressure, Pressure Support, SPN-CPAP/PS	Same
	Spontaneous - Continuous Positive Airway Pressure, Volume Support, SPN-CPAP/VS (optional, part of “Volume ventilation” option)	Spontaneous - Continuous Positive Airway Pressure, Volume Support, SPN-CPAP/VS (optional, part of “Volume ventilation” option)	Same

Topic	*Proposed device* *BABYLOG VN800, BABYLOG VN600*	*Predicate device* *Infinity Acute Care System Workstation Neonatal Care*	*Comments*
	Spontaneous - Continuous Positive Airway Pressure, SPN-CPAP (optional, part of "Non-invasive ventilation" option)	Spontaneous - Continuous Positive Airway Pressure, SPN-CPAP (optional, part of "Non-invasive ventilation" option)	Same
	Spontaneous - Proportional Pressure Support, SPN-PPS (optional)	Spontaneous - Proportional Pressure Support, SPN-PPS (optional)	Same
Additional settings for ventilation	Apnea ventilation	Apnea ventilation	Same
	Trigger	Flow trigger	Same
	Sigh	Sigh	Same
	Volume guarantee (optional, part of "Volume ventilation" option)	Volume Guarantee (optional, part of "Volume ventilation" option)	Same
	ATC (optional)	ATC (optional)	Same
	AutoRelease	AutoRelease	Same
Volume ventilation	Software option which contains PC-MMV and SPN-CPAP/VS and Volume guarantee	Software option which contains PC-MMV and SPN-CPAP/VS and Volume guarantee	Same
Anti-air shower	Reduced flow after detected disconnection until detected reconnection	Reduced flow after detected disconnection until detected reconnection	Same
Maneuvers	• Manual insp./inspiration hold • O2/suctioning • Nebulization (optional)	• Manual inspiration/hold • Suction maneuver • Medication nebulization (optional)	Same

Discussion of Non-clinical Testing

The Babylog VN800 / Babylog VN600 ventilator is a new device and has undergone extensive testing to qualify it with e.g., national and international consensus standards, technical system requirements and other requirements. The following verification and validation activities were deemed necessary to establish substantial equivalence to the predicate device and were carried out under well-established methods, their results summarized in Test Summary tables and the evidence included in this submission.

- Sterilization
- Biocompatibility
- Software, including cybersecurity
- Electrical safety
- Electromagnetic compatibility (EMC)
- Alarm Systems in medical electrical equipment
- Respiratory gas monitors
- Waveforms, including comparisons to the predicate device and performance
- Technical System Requirements, covering:
    - Risk control measures
    - Technical data
    - Essential safety and performance
- Accessories compatibility
- Human factors engineering, usability

Conclusion

The conclusions drawn from non-clinical tests and the comparison of intended use and technological characteristics with its predicate demonstrate that the new product Babylog VN800 / Babylog VN600 is substantially equivalent to the predicate device Infinity Acute Care System Workstation Neonatal Care K093632 and does not raise new questions of safety or effectiveness.

- END -