May 16, 2023

Draegerwerk AG & Co. KGaA
Holger Nadler
Senior Regulatory Affairs Manager
53/55 Moislinger Allee
Luebeck, Schleswig-Holstein 23542
Germany

Re: K222024
Trade/Device Name: Evita V800, Evita V600
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 Holger Nadler:

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)*
K222024

Device Name
Evita V800
Evita V600

Indications for Use *(Describe)*
The Evita intensive care ventilator (Evita V800 / Evita V600) is intended for the ventilation of adults, pediatric patients and neonates weighing a minimum of 0.4 kg (0.88 lb). The device is indicated for patients who require temporary or longer-term breathing support for different medical reasons. The device is intended for stationary use in hospitals and medical rooms or for intrahospital patient transport. The device is intended to be used by qualified and trained medical personnel. The device is indicated to provide critical care specific therapy. The device provides ventilation monitoring and modes for volume controlled, pressure controlled and spontaneous breathing.

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

Official Correspondent: Dr. Bettina Moebius
Head of Regulatory Affairs Central
E-Mail: bettina.moebius@draeger.com
Telephone: +49 451 882 4100

US Agent: Darlene Thibodeau
Head of Quality Assurance and Compliance
E-mail: darlene.thibodeau@draeger.com
Telephone: (978) 773-1060

Date prepared: **16 May 2023**

Device Name: Common name: Ventilator
Trade Name: Evita V800 / Evita V600
Classification Continuous, Facility Use
868.5895
Product Code: CBK, Class: II

Predicate Device: Infinity Acute Care System Workstation Critical Care, K093633

Referenced Device: Puritan Bennett™ 980 Series Ventilator System, K193056 was used as a reference device for extension of flow range for the patient category "adult" in O2 therapy up to 80l/min. The predicate device only supports a flow rate up to 60l/min.

Drägerwerk AG & Co. KGaA is submitting a traditional 510(k) premarket notification for a new device, Evita V800 / Evita V600.

Device Description

The intensive care ventilators Evita V800 and Evita V600 were developed and are manufactured by Dräger in Lübeck, Germany.

Evita V800 and Evita V600 are specified for the ventilation of adults, pediatric patients and neonates. These devices provide mandatory ventilation modes and ventilation modes for supporting spontaneous breathing as well as ventilation monitoring.

Evita V800 and Evita V600 are available in different device variants and can additionally be upgraded by software and hardware options as well as attachable accessories.

Evita V800 and Evita V600 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 Evita intensive care ventilator (Evita V800 / Evita V600) is intended for the ventilation of adults, pediatric patients and neonates weighing a minimum of 0.4 kg (0.88 lb).

The device is indicated for patients who require temporary or longer-term breathing support for different medical reasons. The device is intended for stationary use in hospitals and medical rooms or for intrahospital patient transport. The device is intended to be used by qualified and trained medical personnel. The device is indicated to provide critical care specific therapy. The device provides ventilation monitoring and modes for volume controlled, pressure controlled and spontaneous breathing.

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

Standard Number and Version	Title
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
IEC 60601-1-10 Edition 1.1 2013-11	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers
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

Determination of Substantial Equivalence:

The EVITA V800, EVITA V600 ventilators are substantially equivalent to the predicate Infinity Acute Care System Workstation Critical Care (K093633) and the reference device, Puritan Bennett™ 980 Series Ventilator System, (K1930569), as described in the following table:

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *Infinity Acute Care System Workstation Critical Care*	*Comments*
Device Trade Name	EVITA V800 EVITA V600	Infinity Acute Care System Workstation Critical Care	-
Manufacturer	Drägerwerk AG & Co. KGaA	Drägerwerk AG & Co. KGaA	same as predicate device
510(k) number		K093633	-
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	• Adult • Pediatric • Neonate	• Adult • Pediatric • Neonate	same

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *Infinity Acute Care System Workstation Critical Care*	*Comments*
Intended Use / Indications for Use	The Evita intensive care ventilator (Evita V800 / Evita V600) is intended for the ventilation of adults, pediatric patients and neonates weighing a minimum of 0.4 kg (0.88 lb). The device is indicated for patients who require temporary or longer-term breathing support for different medical reasons. The device is intended for stationary use in hospitals and medical rooms or for intrahospital patient transport. The device is intended to be used by qualified and trained medical personnel. The device is indicated to provide critical care specific therapy. The device provides ventilation monitoring and modes for volume-controlled and pressure-controlled ventilation and spontaneous breathing.	The Infinity Acute Care System Workstations Critical Care consist of monitoring and control displays and additional therapy units. They are intended to be used as integrated, networked, and configurable workstations to provide critical care specific therapy. The Infinity Acute Care System Workstations Critical Care are intended to be used by qualified and trained medical personnel. The Infinity C Series Medical Cockpits, consisting of the C500 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 Series Medical Cockpits are intended to be used in environments where patient care is provided by trained healthcare professionals. **The Evita V500 ventilation unit of the Infinity Acute Care System is intended for the ventilation of adult, pediatric and neonatal patients. Evita V500 offers mandatory ventilation modes and ventilation modes for spontaneous breathing support and airway monitoring**. The Evita V500 ventilation unit is used with Infinity C Series Dräger Medical Cockpits. The Evita V500 ventilation unit is intended for use in different medical care areas.Evita V500 is intended for stationary use in hospitals and medical rooms or for patient transportation within the hospital.	Similar

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *Infinity Acute Care System Workstation Critical 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 Critical Care are intended to be used by qualified and trained medical personnel. The Infinity Series 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.	Intended for stationary use in hospitals and medical rooms or for patient transportation within the hospital. Not intended for use in: - In hyperbaric chambers - For magnetic resonance imaging (MRT, NMR, NMI) - With flammable gases or anesthetic agents - In areas of explosion hazard - In areas with combustible or explosive substances In rooms without adequate ventilation	Similar
Gas supply	Central gas supply	Central gas supply	Same
	Gas cylinders • Transport supply unit (optional) • Gas cylinder holder (optional)	Gas cylinders • Transport supply cart (optional) • Gas bottle holder (optional)	Same
	Gas supply unit GS500 (optional)	Gas supply unit GS500 (optional)	Same
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

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *Infinity Acute Care System Workstation Critical Care*	*Comments*
	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 and expiratory flow/volume	Inspiratory and expiratory flow/volume	Same
	Proximal flow/volume (optional, part of “Neonatal ventilation” option)	Proximal flow/volume (optional, part of “Neonatal ventilation” option)	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
Power supply	Internal battery (NiMH)	Internal battery (NiMH)	Same
	Power supply unit PS500 (optional) • part no. 8418950 lead-acid • part no. 8422900 lithium iron phosphate (LFP)	-	Different
	Battery monitoring	Battery monitoring	Same
	Main switch	Toggle switch	Same
User interface	TFT LCD capacitive touchscreen display	TFT LCD resistive touchscreen display	Different
	Evita V800: 18.5 in display	IACS Medical cockpit C500: 17 in display	Different
	Evita V600: 15.6 in display	IACS Medical cockpit C500: 17 in display	Different
	Rotary knob for selecting, adjusting and confirming	Rotary knob for selecting, adjusting and confirming	Same
	Power supply indicators	Power supply indicators	Similar
	On/off key	On/off key	Same

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *Infinity Acute Care System Workstation Critical Care*	*Comments*
	Operation display	Operation display	Similar
	Graphical user interface including structured screen design and characteristic color scheme	Graphical user interface including structured screen design and characteristic color scheme	Different
	Bed coupling (optional)	-	Different
User interface, screen displays	Waveforms	Curves	Same
	Graphical trends	Graphical trends	
	Tabular trends	Numeric trends	
	Loops	Loops	
	Alarm logbook	Alarm history	
	Logbook	Logbook	
	Numeric parameters	Numeric parameters	
	Lists of measured values and set values	Preconfigured lists of measured values and set values	
	User-specific list for measured values and set values	Customized lists for measured values and set values	
	Smart Pulmonary View (optional)	Smart Pulmonary View (optional)	
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
	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
General monitoring, specific alarms	Alarm, cause, and remedy texts	Alarm, cause, and remedy texts	Different
	Alarm grade and priority score	Alarm grade and priority score	Different
	Set criteria	Set criteria	Different
	User-initiated system test	User-initiated system test	Same

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *Infinity Acute Care System Workstation Critical Care*	*Comments*
Device monitoring	Gas supply	Gas supply	Same
	Power supply	Power supply	Similar
	Device temperature	Device temperature	Same
	Mutual Processor Monitoring	Mutual Processor Monitoring	Same
	Connection to display unit	Connection to display unit	Different
Communication protocols	MEDIBUS	MEDIBUS	Same
	MEDIBUS.X	not available	Different
	MED.X.Comp	not available	Different
Type of patient interface	Invasive ventilation (Tube): – Endotracheal tube (for adults, pediatric patients and neonates) Tracheostomy cannula (for adults and pediatric patients)	Invasive ventilation (Tube): – Endotracheal tube (for adults, pediatric patients and neonates) Tracheostomy cannula (for adults and pediatric patients)	Same
	Non-invasive ventilation (NIV) (optional): – NIV mask (for adults, pediatric patients and neonates) Prongs (for pediatric patients and neonates)	Non-invasive ventilation (NIV) (optional): – NIV mask (for adults, pediatric patients and neonates) Prongs (for pediatric patients and neonates)	Same
	O2 Therapy: – Nasal cannula (for adults, pediatric patients and neonates)	O2 Therapy: – Nasal cannula (for adults, pediatric patients and neonates) Oxygen mask (for adults, pediatric patients and neonates)	Same
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

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *Infinity Acute Care System Workstation Critical Care*	*Comments*
Ventilation modes	Volume Control - Synchronized Intermittent Mandatory Ventilation, VC-SIMV (for neonates only available in combination with AutoFlow)	Volume Control - Synchronized Intermittent Mandatory Ventilation, VC-SIMV (for neonates only available in combination with AutoFlow)	Same
	Volume Control - Assist Control, VC-AC (for neonates only available in combination with AutoFlow)	Volume Control - Assist Control, VC-AC (for neonates only available in combination with AutoFlow)	Same
	Volume Control - Controlled Mandatory Ventilation, VC-CMV (for neonates only available in combination with AutoFlow)	Volume Control - Continuous Mandatory Ventilation, VC-CMV (for neonates only available in combination with AutoFlow)	Same
	Volume Control - Mandatory Minute Ventilation, VC-MMV (optional for Evita V600, for neonates only available in combination with AutoFlow)	Volume Control - Mandatory Minute Ventilation, VC-MMV (optional, for neonates only available in combination with AutoFlow)	Same
	Pressure Control - Synchronized Intermittent Mandatory Ventilation, PC-SIMV	Pressure Control - Synchronized Intermittent Mandatory Ventilation, PC-SIMV	Same
	Pressure Control - Synchronized Intermittent Mandatory Ventilation plus, PC-SIMV+	Pressure Control - Biphasic positive airway pressure, PC-SIMV+	Same
	Pressure Control - Assist Control, PC-AC	Pressure Control - Assist Control, PC-AC	Same
	Pressure Control - Controlled Mandatory Ventilation, PC-CMV (mode available in NIV for neonates)	Pressure Control - Continuous Mandatory Ventilation, PC-CMV (mode available in NIV for neonates)	Same
	Pressure Control - Airway Pressure Release Ventilation, PC-APRV (optional for Evita V600)	Pressure Control - Airway Pressure Release Ventilation, PC-APRV (optional)	Same

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *Infinity Acute Care System Workstation Critical Care*	*Comments*
	Pressure Control - Pressure Support Ventilation, PC-PSV (optional)	Pressure Control - Pressure Support Ventilation, PC-PSV (optional)	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	Spontaneous - Continuous Positive Airway Pressure, Volume Support, SPN-CPAP/VS	Same
	Spontaneous - Continuous Positive Airway Pressure, SPN-CPAP (optional, mode only available in NIV for neonates)	Spontaneous - Continuous Positive Airway Pressure, SPN-CPAP (optional, mode only available in NIV for neonates)	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
	AutoFlow (optional for Evita V600)	AutoFlow (optional)	Same
	Volume guarantee	Volume Guarantee	Same
	ATC (optional for Evita V600)	ATC (optional)	Same
	AutoRelease	AutoRelease	Same
	Variable PS (optional)	Variable PS (optional)	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	Manual inspiration/hold	Same
	Expiration hold	Exp. Hold (Expiratory hold)	Same
	O2/suctioning	Suction maneuver	Same

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *Infinity Acute Care System Workstation Critical Care*	*Comments*
	Manual disconnection	Manual disconnection	Same
	Nebulization (optional)	Medication nebulization (optional)	Same
	Measurement maneuver Low-flow PV loop (optional)	Low Flow PV Loop (optional)	Same
	Diagnostics - measurement maneuver • Measurement of intrinsic PEEP (PEEPi) • Measurement of occlusion pressure (P0.1) • Measurement of maximum inspiratory effort of the patient (NIF)	Diagnostic functions: • Intrinsic PEEP measurement • Occlusion pressure measurement • NIF measurement	Same
Software option for weaning process	SmartCare/PS: knowledge-based system for the automated control of pressure support in SPN-CPAP/PS (optional)	SmartCare/PS: knowledge-based system for the automated control of pressure support in SPN-CPAP/PS (optional)	Same

Substantial Equivalence to the reference device, Puritan Bennett™ 980			
Specification	Reference Device Puritan Bennett™ 980 Series Ventilator System K193056	Proposed device EVITA V800, EVITA V600 K222024	Discussion of Differences
O2 Therapy	O2 therapy (High Flow Oxygen Therapy) delivers heated and humidified gas at a set FiO2 and flow rate through an unsealed heated patient interface.	O2 therapy (High Flow Oxygen Therapy) delivers heated and humidified gas at a set FiO2 and flow rate through an unsealed heated patient interface. • Configurable start values per patient category • Limitation of maximum pressure can be set	Substantially equivalent – O2 therapy (High Flow Oxygen Therapy) is substantially equivalent to the reference device Puritan Bennett PB980. The technology for the delivery of High Flow Oxygen Therapy, which is delivery of a set oxygen concentration (FiO2) at a fixed flow rate, is not novel or new to the ventilator. The intended patient for High Flow Oxygen Therapy on both products is a spontaneously breathing patient. A humidifier is required for the delivery of High Flow Oxygen Therapy from both ventilators. The O2 Therapy function on the subject as well as on the reference device is available for adult, pediatric and neonatal patients.
High Flow Oxygen Therapy Flow Rate	Adult: 1 to 80 liters/minute	Adult: 2 to 80 liters/minute	Equivalent to the Puritan Bennett PB980 The flow range was narrowed slightly (lower end of the flow rate is 2LPM instead of 1 LPM in the Puritan Bennett PB980). This does not affect the safety or performance of this feature. Testing has been completed as documented in the 510(k) to demonstrate the device meets these specifications.

Discussion of Non-clinical Testing

The Evita V800 / Evita V600 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 Evita V800 / Evita V600 is substantially equivalent to the predicate device Infinity Acute Care System Workstation Critical Care K093633 and raises no differences of safety or effectiveness.

- END -