May 7, 2026

Draegerwerk AG & CO Kgaa
Holger Nadler
Ragulatory Affairs Manager
Moislinger Allee 53-55
Luebeck, 23
Germany

Re: K253647
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: November 17, 2025
Received: November 20, 2025

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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

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

Sincerely,

John S. Bender -S

for Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253647

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.

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

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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

Contact Person: Holger Nadler
Regulatory Affairs Manager
E-Mail: holger.nadler@draeger.com
Telephone: +49 451 882 6856

Date prepared: April 9, 2026

This 510(k) Summary is being submitted in accordance with 21 CFR 807.92.

Device Name: Common name: Ventilator
Trade Name: Evita V800 / Evita V600
Classification name: Continuous ventilator
Regulation Number: 21 CFR §868.5895
Product Code: CBK (Ventilator, Continuous, Facility Use)
Class: II

Predicate Device: Evita V800, Evita V600, K222024

Reference device: Getinge Maquet Servo-U K180098

Device Description

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 with a basic device configuration that comprises

the following:

– Display unit (graphical user interface)

– Ventilation unit with Software

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.

The intended use is unchanged compared to the predicate device (K222024)

Technological Characteristics and Differences vs Predicate

Ventilation/Functions

Decelerating-flow setting in VC modes (setting only; no new mode; comparable to SERVO-U/n 2.1, K180098). Additionally, the subject device introduces: selectable minute-volume alarm source (inspiratory/expiratory/leakage-corrected; default expiratory); simultaneous adjustment of alarm limits for MV/RR/VT (“Autoset”); an automated driving-pressure procedure (calculates Pplat, Pdrive, Cstat; display/decision-support only); and a PEEP/FiO2 view (display-only, no therapy control).

Comparable to SERVO-U/n 2.1 (K180098: ‘Volume Control improvements including decelerating flow’)

User interface and usability

GUI harmonization with unchanged “Touch–Turn–Confirm” operating principle; summative usability validation per IEC 62366-1 confirms no new use-related risks

Infrastructure/Maintenance

O2-sensor calibration additionally possible via GS500 (same algorithm as predicate); server-triggered software update available in addition to local service-PC; NTP time synchronization added (no therapy impact)

Alarms

Tidal-volume alarms: derived limits applied under defined criteria; alarm texts consolidated/clarified; configurable priorities within controlled bounds; underlying detection logic, thresholds, and timing unchanged

Software implementation (no functional change)

SmartCare/PS migrated from Java to MATLAB/Simulink; algorithm behavior, alarms, thresholds, and IFU remain unchanged; equivalence verified by software V&V

Hardware/Labeling/Accessories

Supplier-driven material updates (e.g., sealing ring 8416067, flow-sensor cable plug handle) with biocompatibility confirmed; air-inlet labeling updated (“Do not obstruct” +

warning symbol); accessories list cleaned; PS500 LFP battery replacement interval extended from 4 to 6 years based on test data; no new risks introduced

List of Consensus Standards

Standard Number and Version	Title
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	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 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	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
IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION	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 80601-2-12 Third edition 2023-11	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 80601-2-55 Second edition 2018-02 [Including AMD1:2023]	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitor [Including Amendment 1 (2023)].
ISO 80601-2-90 First edition 2021-08	Medical electrical equipment - Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment
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 1.1 2020-06 CONSOLIDATED VERSION	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

Standard Number and Version	Title
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
ISO 18562-1 Second edition 2024-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
ISO 18562-2 Second edition 2024-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
ISO 18562-3 First edition 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
ISO 18562-3 Second Edition 2024-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
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
ISO 17664-1 First edition 2021-07	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
ISO 17664-2 First edition 2021-02	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.

Comparison to Predicate

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *EVITA V800, EVITA V600*	*Comments*
Device Trade Name	EVITA V800 EVITA V600	EVITA V800 EVITA V600	-
Manufacturer	Drägerwerk AG & Co. KGaA	Drägerwerk AG & Co. KGaA	Same
510(k) number		K222024	-
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* *EVITA V800, EVITA V600*	*Comments*
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.	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.	Intended Use unchanged
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 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.	Same

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *EVITA V800, EVITA V600*	*Comments*
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 – In vehicles, airplanes, helicopters, and on ships Do not operate the device with helium or helium mixtures.	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.	Same
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	Gas supply unit GS500	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
	Pneumatic nebulizer (optional, part of “Nebulizer” option)	Pneumatic nebulizer (optional, part of “Nebulizer” option)	Same
	Inspiratory and expiratory pressure	Inspiratory and expiratory pressure	Same

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *EVITA V800, EVITA V600*	*Comments*
Pressure and volume monitoring	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	2 ambient pressure sensors	Same
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
PEEP/FiO2 view (display-only)	Added	Not available	Different; no therapy control
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 • part no. 6873570 CO2 mainstream sensor	Same
Power supply	Internal battery (NiMH)	Internal battery (NiMH)	Same
	Power supply unit PS500 • part no. 8418950 lead-acid • part no. 8422900 lithium iron phosphate (LFP)	Power supply unit PS500 • part no. 8418950 lead-acid • part no. 8422900 lithium iron phosphate (LFP)	Same
	Battery monitoring	Battery monitoring	Same
	Main switch	Main switch	Same
Battery maintenance interval (LFP)	6 years	4 years	Different; supported by test reports; hardware unchanged

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *EVITA V800, EVITA V600*	*Comments*
User interface	TFT LCD capacitive touchscreen display • Evita V800: 18.5 in • Evita V600: 15.6 in	TFT LCD capacitive touchscreen display • Evita V800: 18.5 in • Evita V600: 15.6 in	Same
	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
	Graphical user interface including structured screen design and characteristic color scheme	Graphical user interface including structured screen design and characteristic color scheme	Same
GUI harmonization	Updated layout	Previous layout	Different; summative HFE per IEC 62366-1
User interface, screen displays	Waveforms	Waveforms	Same
	Graphical trends	Graphical trends	
	Tabular trends	Tabular trends	
	Loops	Loops	
	Alarm logbook	Alarm logbook	
	Logbook	Logbook	
	Numeric parameters	Numeric parameters	
	Lists of measured values and set values	Lists of measured values and set values	
	User-specific list for measured values and set values	User-specific list for measured values and set values	
	Smart Pulmonary View	Smart Pulmonary View	
	Optical and acoustical alarm indication	Optical and acoustical alarm indication	Same

Topic	*Proposed device EVITA V800, EVITA V600*	*Predicate device EVITA V800, EVITA V600*	*Comments*
General monitoring, alarm principles	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	Same
	Alarm grade and priority score	Alarm grade and priority score	
	Set criteria	Set criteria	
Minute-volume alarm source	Selectable (default exp.)	Expiratory only	Different; underlying detection/thresholds unchanged
Autoset (MV/RR/VT limits)	Available	Not available	Different; ranges unchanged; UI confirmation; validated
Tidal-volume alarms: derived limits/texts/priorities	Derived limits under criteria; texts consolidated; priorities configurable within bounds	Legacy texts; fixed priorities	Different; detection logic/timing unchanged
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	MEDIBUS.X	
	MED.X.Comp	MED.X.Comp	

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *EVITA V800, EVITA V600*	*Comments*
NTP time synchronization	Added (no therapy impact)	Not available	Different; cybersecurity assessed
Maintenance / Software update			
Server-triggered software update	Available in addition to service-PC	Service-PC only	Different; authenticated/integrity-protected
Therapy types	Invasive ventilation (Tube)	Invasive ventilation (Tube)	Same
	Non-invasive ventilation (NIV)	Non-invasive ventilation (NIV)	Same
	O2 Therapy	O2 Therapy	Same
Ventilation modes	Volume Control - Synchronized Intermittent Mandatory Ventilation, VC-SIMV	Volume Control - Synchronized Intermittent Mandatory Ventilation, VC-SIMV	Same
	Volume Control - Assist Control, VC-AC	Volume Control - Assist Control, VC-AC	Same
	Volume Control - Controlled Mandatory Ventilation, VC-CMV	Volume Control - Controlled Mandatory Ventilation, VC-CMV	Same
	Volume Control - Mandatory Minute Ventilation, VC-MMV	Volume Control - Mandatory Minute Ventilation, VC-MMV	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 - Synchronized Intermittent Mandatory Ventilation plus, PC-SIMV+	Same

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *EVITA V800, EVITA V600*	*Comments*
	Pressure Control - Assist Control, PC-AC	Pressure Control - Assist Control, PC-AC	Same
	Pressure Control - Controlled Mandatory Ventilation, PC-CMV	Pressure Control - Controlled Mandatory Ventilation, PC-CMV	Same
	Pressure Control - Airway Pressure Release Ventilation, PC-APRV	Pressure Control - Airway Pressure Release Ventilation, PC-APRV	Same
	Pressure Control - Pressure Support Ventilation, PC-PSV	Pressure Control - Pressure Support Ventilation, PC-PSV	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, SPN-CPAP	Spontaneous - Continuous Positive Airway Pressure, SPN-CPAP	Same
	Spontaneous - Continuous Positive Airway Pressure, Volume Support, SPN-CPAP/VS	Spontaneous - Continuous Positive Airway Pressure, Volume Support, SPN-CPAP/VS	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 for Evita V600)	Same

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *EVITA V800, EVITA V600*	*Comments*
	Volume guarantee	Volume Guarantee	Same
	ATC (optional for Evita V600)	ATC (optional for Evita V600)	Same
	AutoRelease	AutoRelease	Same
	Variable PS (optional)	Variable PS (optional)	Same
Decelerating-flow (VC modes)	Available (setting only)	Not available as manual setting	Different; comparable to Servo-U (K180098); bench, waveform met acceptance
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 insp./inspiration hold	Same
	Expiration hold	Expiration hold	Same
	O2/suctioning	O2/suctioning	Same
	Manual disconnection	Manual disconnection	Same
	Nebulization	Nebulization	Same
	Measurement maneuver Low-flow PV loop (optional)	Measurement maneuver 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)	Diagnostics - measurement maneuver • Measurement of intrinsic PEEP (PEEPi) • Measurement of occlusion pressure (P0.1) • Measurement of maximum inspiratory effort of the patient (NIF)	Same
Driving pressure	Automated	Manual evaluation only	Different; automates existing maneuver; verified/validated

Topic	*Proposed device* *EVITA V800, EVITA V600*	*Predicate device* *EVITA V800, EVITA V600*	*Comments*
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
Implementation language	MATLAB/Simulink	Java	Different (implementation only); algorithm/alarms unchanged; V&V equivalence
Gas pathway			
Gas inlet sealing ring material	Material FKM V80G1	Material FKM V80G2	Different; biocompatibility confirmed
Air-inlet filter assembly	New supplier; strap & silicone seal	Previous supplier	Different; verification/biocompatibility passed
Accessories/Materials/ Labeling			
Flow-sensor cable plug handle material	Ultradur B4521 PRO	Ultradur B4520 PRO	Different; biocompatibility confirmed
Air-intake labeling	Do not obstruct' plus prohibition symbol; location unchanged; labeling only	EMERGENCY – AIR INTAKE	Different; compliance with ISO 80601-2-12; no functional change
Accessories list	Removed flex hoses	Listed hoses	Different; misuse risk mitigated; labeling updated

Discussion of Non-clinical Testing

The Evita V800 / Evita V600 ventilator is a modified 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
- Critical care ventilators standard
- Respiratory gas monitors
- Technical System Requirements, covering:
  - Risk control measures
  - Technical data
  - Essential safety and performance
- Accessories compatibility
- Human factors engineering, usability

Clinical Performance Data

Clinical performance data: None required to support substantial equivalence.

Conclusion

Based on the intended use, technological characteristics, and non-clinical performance testing, the Evita V800/V600 subject device is as safe and effective as the predicate device (K222024) and is substantially equivalent. Identification of Servo-U (K180098) as a reference device supports the decelerating-flow setting comparison.

- END -