April 4, 2025

Draegerwerk AG & Co. KGaA
Jan Upmeier
Regulatory Affairs Manager
Moislinger Allee 53-55
Luebeck, SH 23542
Germany

Re: K242769
Trade/Device Name: VentStar Resus heated (N) (MP17030); VentStar Autobreath heated (N) (MP17031)
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: Class II
Product Code: BTL, BZE
Dated: September 12, 2024
Received: September 13, 2024

Dear Jan Upmeier:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
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Office of Product Evaluation and Quality
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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)*
K242769

Device Name
VentStar Resus heated (N) (MP17030);
VentStar Autobreath heated (N) (MP17031)

Indications for Use *(Describe)*

VentStar Resus heated (N) (MP17030):
VentStar Resus heated (N) with manual PEEP valve is a disposable breathing circuit for conveying breathing gas from a breathing gas source (resuscitation module) via the Fisher & Paykel MR850 humidifier to a patient.
The product allows short-term ventilation with humidified breathing gas and additional PEEP.
It can be connected to a breathing mask, a laryngeal mask, or an endotracheal tube via the patient port.
The product is suitable for patients with a maximum body weight of 10 kg (22 lb).

VentStar Autobreath heated (N) (MP17031):
VentStar AutoBreath heated (N) with automatic PEEP valve is a disposable breathing circuit for conveying breathing gas from a breathing gas source resuscitation module) via the Fisher & Paykel MR850 humidifier to a patient.
The product allows automatic short-term ventilation with humidified breathing gas and additional PEEP.
The valve is controlled via the AutoBreath function of the resuscitation module. The product can be connected to a breathing mask, a laryngeal mask, or an endotracheal tube via the patient port.
The product is suitable for patients with a maximum body weight of 10 kg (22 lb).

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: 02 April 2025

Device Name:

Trade Name:	VentStar Autobreath heated (N) / VentStar Resus heated (N)
Classification Name:	Powered Emergency Ventilator
Regulation Number:	21 CFR 868.5925
Class:	II

Predicate Device:

Primary predicate device:	900RD010 - Fisher & Paykel's S/USE RESUS KIT W/O MSK (10), cleared via K892885
Secondary predicate device:	VentStar Helix heated (N) Plus (MP02608), cleared via K222822
Reference device for VentStar Autobreath heated (N):	MU10841 Breathing hose for Resuscitaire with AutoBreath, disposable, 25 pcs., Draeger Medical Systems Inc., cleared via K120642

Device Description

The subject devices, VentStar Autobreath heated (N) (MP17031) and VentStar Resus heated (N) (MP17030), are two heated disposable single limp breathing circuits with humidifier chamber for connection to the humidifier MR850 by Fisher and Paykel (K073706), for neonatal patients with a maximum body weight of 10 kg for use with the Dräger BabyRoo TN300 (K230278) and Dräger Resuscitaire (K120642).

The VentStar Resus heated (N) MP17030 is equipped with a manual PEEP valve which enables the setting of a PEEP by the operator directly. The operator can control the inhalation and exhalation.

The VentStar Autobreath heated (N) MP17031 is equipped with an automatic PEEP valve. With the Autobreath function a respiratory rate can be adjusted on the resuscitation module and a machine controlled consistent inspiration rate can be applied to the patient.

The heated breathing circuits are intended for conveying breathing gases (air and/or oxygen) from a breathing gas source (resuscitation module) to the humidifier chamber and finally to the patient.

Both breathing circuits are designed for a flow range from 5 to 15 L/min.

The heating of the hoses is done by using electrical heating wires inside the wall of the hoses. These wires have specific electrical resistances to generate a specific heating power. The heating plate of the humidifier chamber is positioned at the heater of the humidifier.

Indications for Use

VentStar Resus heated (N) (MP17030): VentStar Resus heated (N) with manual PEEP valve is a disposable breathing circuit for conveying breathing gas from a breathing gas source (resuscitation module) via the Fisher & Paykel MR850 humidifier to a patient.

The product allows short-term ventilation with humidified breathing gas and additional PEEP.

It can be connected to a breathing mask, a laryngeal mask, or an endotracheal tube via the patient port.

The product is suitable for patients with a maximum body weight of 10 kg (22 lb).

VentStar Autobreath heated (N) (MP17031): VentStar AutoBreath heated (N) with automatic PEEP valve is a disposable breathing circuit for conveying breathing gas from a breathing gas source resuscitation module) via the Fisher & Paykel MR850 humidifier to a patient.

The product allows automatic short-term ventilation with humidified breathing gas and additional PEEP.

The valve is controlled via the AutoBreath function of the resuscitation module. The product can be connected to a breathing mask, a laryngeal mask, or an endotracheal tube via the patient port.

The product is suitable for patients with a maximum body weight of 10 kg (22 lb).

Environments of use

The devices are intended for use in hospitals, labor and delivery units, and medical rooms.

Comparison to Predicate

Drägerwerk AG & Co KGaA concludes that VentStar Resus heated (N) (MP17030) and VentStar Autobreath heated (N) (MP17031) in Table 1 are substantially equivalent to the Fisher & Paykel's product REF 900RD010 (K892885) and the Drägerwerk AG & Co. KGaA's product REF MP02608 (K222822).

Table 1: Comparison Table VentStar Resus heated (N) (MP17030) and VentStar Autobreath heated (N) (MP17031)

Substantial Equivalence Discussion	Subject of Submission	Primary predicate Device (K892885)	Secondary predicate device (K222822)	Reference Device (K120642)	Comments		
					900RD110	MP02608	MU10841
Product Name	MP17030/MP17031	REF 900RD010	MP02608	MU10841	-	-	-
510(k) No.	K242769	K892885	K222822	K120642	-	-	-
Intended use/ Indications for use	**MP17030:** VentStar Resus heated (N) with manual PEEP valve is a disposable breathing circuit for conveying breathing gas from a breathing gas source (resuscitation module) via the Fisher & Paykel MR850 humidifier to a patient. The product allows short-term ventilation with humidified breathing gas and additional PEEP. It can be connected to a breathing mask, a laryngeal mask, or an endotracheal tube via the patient port. The product is suitable for patients with a maximum body weight of 10 kg (22 lb). **MP17031:** VentStar AutoBreath heated (N) with automatic PEEP valve is a disposable breathing circuit for conveying breathing gas from a breathing gas source resuscitation module) via the Fisher & Paykel MR850 humidifier to a patient. The product allows automatic short-term ventilation with humidified breathing gas and additional PEEP. The valve is controlled via the AutoBreath function of the resuscitation module. The product can be connected to a breathing mask, a laryngeal mask, or an endotracheal tube via the patient port. The product is suitable for patients with a maximum body weight of 10 kg (22 lb).	The F&P Classic T-piece Circuit (900RD010) is a single use breathing circuit intended to provide ventilatory support to neonates and infants with respiratory insufficiency. The device is designed to connect to the F&P Neopuff T-piece Resuscitator or any other gas-powered resuscitator compliant to ISO-10651-5:2006. This device is designed for use in the hospital environment and must be prescribed by a physician. It is intended to be used by medical professionals including physicians, nurses, midwives and respiratory therapists. The intended population for use is neonates and infants.	VentStar Helix heated (N) Plus (MP02608): Inspiratory heated disposable breathing circuit with humidifier chamber for connection to a humidifier MR850 by Fisher & Paykel, for neonatal patients with a tidal volume of up to 100 mL, for conducting humidified breathing gas from humidifier to patient.	The disposable breathing circuit is designed for AutoBreath functionality. It is a disposable breathing circuit for the transmission of breathing gases between a breathing gas source (resuscitation module) and a neonate. It is intended for short term resuscitation in the Labor and Delivery department. It is designed for use with patients up to a maximum body weight of 10 kg (22 lbs.).	Similar	Similar	Similar

Substantial Equivalence Discussion	Subject of Submission	Primary predicate Device (K892885)	Secondary predicate device (K222822)	Reference Device (K120642)	Comments		
					900RD110	MP02608	MU10841
Product Name	MP17030/MP17031	REF 900RD010	MP02608	MU10841	-	-	-
Description	Disposable breathing circuit for use with a resuscitation module	Disposable breathing circuit for use with a resuscitation module	Single-heated breathing circuits with humidifier chamber	Disposable breathing circuit	Identical	Similar	Similar
Heater	for connection to a Fisher & Paykel humidifier MR850	none	for connection to a Fisher & Paykel humidifier MR850/MR810	none	Different	Identical	Different
Patient Population	Neonates with a maximum body weight of 10 kg (22 lb).	Neonates with a maximum body weight of 10 kg (22 lb).	Neonates with a maximum body weight of 10 kg (22 lb).	The patient target groups of the connected main device apply to this product. They are listed in the instructions for use for the main device.	Identical	Identical	Identical
Application	disposable	disposable	disposable	disposable	Identical	Identical	Identical
Hose diameter ID = Inner Diameter	12 mm ID	12 mm ID	12 mm ID	10 mm ID	Identical	Identical	Different
Color	blue spiral on colorless hose	transparent	Inspiratory limb: blue spiral on colorless hose	Inspiratory limb: transparent	Similar	Identical	Different
Heating Wire	In the wall of the circuit	none	In the wall of the circuit	none	Different	Identical	Different
Connectors	ISO 5356-1 Conical Connectors	ISO 5356-1 Conical Connectors	ISO 5356-1 Conical Connectors	ISO 5356-1 Conical Connectors	Identical	Identical	Identical
Patient Connector	ISO cone 15 mm according to ISO 5356-1	15 mm medical taper	Y-piece with ISO cone 15 female according to ISO 5356-1	ISO cone 15 female according to ISO 5356-1	Identical	Identical	Identical

Substantial Equivalence Discussion	Subject of Submission	Primary predicate Device (K892885)	Secondary predicate device (K222822)	Reference Device (K120642)	Comments		
					900RD110	MP02608	MU10841
Product Name	MP17030/MP17031	REF 900RD010	MP02608	MU10841	-	-	-
Device Connector	ISO cone 15 mm according to ISO 5356-1	10 mm medical taper	11.5 female (ID) connector according to ISO 5356-1	ISO cone 15 mm male	Different	Identical	Identical
Length Inspiratory Line Humidifier Connection	 1.80 m (70.86 inch) including 0.20 m (7.87 inch) extension line 1.00 m (39.37 inch)	 1.60 m (63 inch) none	1.70 m ±10% (66,9 inch ±10%), including 40 cm (15.74 in) hose extension. 0.50 m ± 40 mm (19.7 ±1.58 inch)	 0.97 m (38.19 in) none	Different	Similar	Different
T-piece functionality to adjust PEEP	MP17030: manual MP17031: automatic PEEP controlled by resuscitation module	manual	-	automatic PEEP controlled by resuscitation module	Identical (MP17030); Different (MP17031)	-	Identical (MP17031)
Resistance	at 2.5 L/min < 0.07 mbar	at 15 L/min 0.64 mbar	at 2.5 L/min < 0.1 mbar	at 2.5 L/min 0.74 mbar/L/min at 15 L/min 0.12 mbar/L/min	Different	Identical	Different
Compliance	at 60 mbar <1,5 mL/mbar	2.23 mL/mbar/m	at 60 mbar (breathing circuit: inspiration and expiration) < 1.0 mL/hPa	at 60 mbar <1.5 mL/mbar	Different	Different	Similar
Positive End Expiratory Pressure (PEEP)	MP17030: 5 L/min <1 to 3 mbar 7 L/min <1 to 5 mbar 9 L/min <2 to 7 mbar MP17031: The PEEP value is set at the TN300 which automatically controls the respiratory rate at the set value.	5 L/min N/A not possible with Neopuff module 8 L/min 1 to 10 mbar 10 L/min 2 to 13 mbar 15 L/min 4 to 14 mbar	-	The PEEP value is set at the TN300 which automatically controls the respiratory rate at the set value.	Similar	-	Identical

Traditional 510(k) 510(k) Summary

Substantial Equivalence Discussion	Subject of Submission	Primary predicate Device (K892885)	Secondary predicate device (K222822)	Reference Device (K120642)	Comments		
					900RD110	MP02608	MU10841
Product Name	MP17030/MP17031	REF 900RD010	MP02608	MU10841	-	-	-
Warm up Time	30 min	-	30 min	-	Different	Identical	-
Humidification Output	Invasive ventilation at 5 to 15 L/min > 33 mg/L Non-invasive ventilation at 5 to 15 L/min > 12 mg/L	-	Invasive ventilation at 2 to 60 L/min > 33 mg/L Non-invasive ventilation at 2 to 60 L/min > 12 mg/L	-	-	Identical	-
Breathing gas temperature at T-Piece	Adjusted and controlled by Fisher & Paykel MR850 humidifier	-	Adjusted and controlled by Fisher & Paykel MR850 humidifier	-	-	Identical	-
Material	Breathing hoses: PP, TPO Connections: TPE Humidifier chamber: ABS, AL, PE, PC, PP, PVC, SI, TPR Manual PEEP Valve: PC, stainless steel, PTFE Automatic PEEP Valve: PC, SI (VMQ), PVC, PSU All breathing gas-conducting components are free of PVC	Hoses: polycarbonate, acetal, polystyrene, stainless steel, copper Chamber Plastic/Alloy	Breathing hoses: EVA, PE, TPE Connections: PE, EVA Y-piece: PP Humidifier chamber: PP, SBC, PVC, ABS, silicone, aluminum All gas-conducting components are free of PVC	Breathing hoses: PE Connections: PP, SBC Automatic PEEP valve: PC, SI, PVC, PSU All gas-conducting components are free of PVC	Similar	Similar	Similar

The indications for use and fundamental scientific technology are the same for the proposed and predicate devices.

Performance Data

Non-clinical testing of the breathing circuits was performed covering mechanical, thermal safety, environmental conditions, electrical safety and electromagnetic compatibility, functional verification, and performance capacity and accuracy. Verification and validation testing was conducted in conformance to the FDA recognized standards as listed below. Performance data related to each proposed modification has been tested and evaluated.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted for VentStar Autobreath heated (N) and VentStar Resus heated (N). The devices comply with the IEC 60601-1 for basic safety and performance and the IEC 60601-1-2 standard for EMC.

Further Performance Testing

To demonstrate performance and functionality, VentStar Autobreath heated (N) and VentStar Resus heated (N) were tested and meet all applicable requirements of the following standards:

- ISO 5367: Anaesthetic and respiratory equipment -- Breathing sets and connectors
- ISO 80601-2-74: Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment (Gap Analysis)
- ISO 10651-5: Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 5: Gas-powered emergency resuscitators
- ISO 5356-1: Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets
- ISO 80369-1: Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements
- ISO 18190: Anaesthetic and respiratory equipment - General requirements for airways and related equipment

Biocompatibility Testing

All materials used in the fabrication of the heated breathing systems and also the completed products were evaluated through biological qualification safety tests as outlined in ISO 10993-1 “Biological Evaluation of Medical Devices” and the international standard series of ISO 18562 “Biocompatibility evaluation of breathing gas pathways in healthcare”. These materials were also tested in accordance with industry recognized test methods and were found to be acceptable for the intended use. The following tests were performed:

- Test for emissions of particulate matter (PM) according to ISO 18562-2
- Test for emission of VOC with additional humidity according to ISO 18562-3
- Test for leachables in condensate according to ISO 18562-4
- Material characterization according to ISO 10993-18 (2009-08) (organic and inorganic extractables/ leachables)
- Cytotoxicity according to ISO 10993-5
- Sensitization according to ISO 10993-10
- Irritation according to ISO 10993-10

List of Consensus Standards

Standards Number	Standards Title	FDA Recognition No. + date
ISO 10993-1 Fifth Edition 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2-258 01/14/2019
ISO 18562-1 First Edition 2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process	1-134 06/07/2018
IEC 60601-1-2 Edition 4.1 2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-36 12/21/2020
ISO 18190 First Edition 2016	Anaesthetic and respiratory equipment - General requirements for airways and related equipment	1-120 01/14/2019
ANSI AAMI ES60601-1 2005/(R)2012 [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]	19-46 05/30/2022
ISO 80601-2-74 Second Edition 2021-07	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment	1-177 05/29/2024
IEC 60601-1-6 Edition 3.2 2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-132 12/21/2020

Standards Number	Standards Title	FDA Recognition No. + date
IEC 62366-1 Edition 1.1 2020-06	Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	5-129 07/06/2020
ISO 5356-1 Third Edition 2004	Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets	1-62 03/16/2012
ISO 5367 Fifth Edition 2014	Anaesthetic and respiratory equipment -- Breathing sets and connectors	1-103 08/14/2015
ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices	5-125 12/23/2019
ISO 10651-5 First Edition 2006-02-01	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 5: Gas-powered emergency resuscitators	1-72 03/16/2012
ISO 80369-1 Second Edition 2018-11	Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	5-121 01/14/2019
ISTA 3A 2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less	5-126 07/06/2020

Conclusion

Based on the indications for use/intended use, technological characteristics, performance/non-clinical testing, and comparison to the predicate devices, the subject devices are substantially equivalent to the legally marketed predicate devices.

- END -