June 14, 2023

Dräegerwerk AG & Co. KGaA
Jan Upmeier
Regulatory Affairs Manager
Moislinger Allee 53-55
Luebeck, Schleswig-Holstein 23542
Germany

Re: K222822
Trade/Device Name: VentStar Helix dual heated N Exten. Kit (MP02280),
VentStar Helix heated (N) Plus (MP02608)
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing system heater
Regulatory Class: Class II
Product Code: BZE
Dated: May 17, 2023
Received: May 17, 2023

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 (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,

Ethan L. Nyberg -S

for James J. Lee, Ph.D.
Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222822

Device Name
VentStar Helix Dual heated N Exten. Kit / VentStar Helix heated (N) Plus

Indications for Use *(Describe)*
VentStar Helix dual heated N Exten. Kit (MP02280): Inspiratory and expiratory 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.

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.

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.

510(k) Premarket Notification Summary

Submitter:

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

Contact Person:

Jan Upmeier
Regulatory Affairs Manager
E-Mail: jan.upmeier@draeger.com
Telephone: +49 451 882 8474

Applicant's US Contact Person:

Darlene Thibodeau
Head of Quality Assurance and Compliance
E-Mail: darlene.thibodeau@draeger.com
Telephone: 978 773-1060

Date prepared:

June 14th, 2023

Device Name:

Trade Name:	VentStar Helix Dual Heated N Exten. Kit / VentStar Helix Heated (N) Plus
Classification Name:	Breathing system heater
Regulation Number:	21 CFR 868.5270
Product Code:	BZE
Class:	II

Predicate Device:

Primary predicate for VentStar Helix Dual Heated N Exten. Kit: RT265 Dual Heated Infant Breathing Circuit, Fisher & Paykel HealthCare, cleared via K103767;
Secondary predicate for VentStar Helix Heated (N) Plus: MP00308 VentStar heated (N), Drägerwerk AG & Co. KGaA, cleared via K102618

Device Description

The subject devices (VentStar Helix Dual Heated N Exten. Kit and VentStar Helix Heated (N) Plus), two inspiratory (and expiratory) heated disposable breathing circuits with humidifier chamber are designed for neonatal patients with a tidal volume of up to 100 mL, for conduction of humidified breathing gas from the humidifier to the patient. VentStar Helix Dual Heated N Exten. Kit is a dual heated breathing circuit and VentStar Helix Heated (N) Plus is a single heated breathing circuit to be connected to a humidifier MR850 by Fisher and Paykel, both tested for system compatibility and released for use with Dräger Babylog VN-Series ventilators.

Additionally, this submission comprises a neonatal humidifier chamber and a double connector for connection to the ventilators as accessories to the above mentioned medical devices.

Indications for Use

VentStar Helix dual heated N Exten. Kit (MP02280): Inspiratory and expiratory 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.

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.

Environments 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:

– Magnetic resonance imaging

– During electrocautery

Comparison to Predicate

Drägerwerk AG & Co KGaA concludes that VentStar Helix Dual Heated N Exten. Kit (MP02280) in Table 1 is substantial equivalent to the Fisher & Paykel's product REF RT265 (K103767) and VentStar Helix heated (N) Plus (MP02608) in Table 2 is substantial equivalent to the Drägerwerk AG & Co KGaA's VentStar heated (N) REF MP00308 (K102618).

Table 1: Comparison Table VentStar Helix Dual Heated N Exten. Kit (MP02280)

Substantial Equivalence Discussion	Subject of Submission	Primary Predicate Device	Comments
Product Name	MP02280	REF RT265	-
510(k) Number	K222822	K103767	-
Indications for use	VentStar Helix dual heated N Exten. Kit (MP02280): Inspiratory and expiratory 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 dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of infant patients, and to maintain the temperature of humidified inspired gas. The RT265 is used for flow rates greater than 4 L/min, and the RT266 is for flow rates between 0.3 and 4 L/min.	Similar
Description	Dual-heated breathing circuits with humidifier chamber	Dual-heated breathing circuits with humidifier chamber	Same
Heater	for connection to a Fisher & Paykel humidifier MR850	for connection to a Fisher & Paykel humidifier MR850	Same
Patient Population	Neonatal patients with a tidal volume of up to 100 mL and a weight up to 8 kg.	Infants, tidal volume <185 mL	Similar
Application	Disposable	disposable	Same
Hose diameter ID = Inner Diameter OD = Outer Diameter	11 mm ID	10 mm ID	Different
Color	Inspiratory limb: blue spiral on colorless hose Expiratory limb: white spiral on colorless hose	Inspiratory limb: blue-transparent Expiratory limb: white	Similar
Heating Wire	Inspiratory limb: in the wall of the circuit Expiratory limb: in the wall of the circuit	Inspiratory limb: Spiral wire inside the circuit Expiratory limb: Spiral wire inside the circuit	Different
Connectors	ISO 5356-1 Conical Connectors	ISO 5356-1 Conical Connectors	Same
Patient Connector	Y-piece with ISO cone 15 mm female according to ISO 5356-1	Y-piece with ISO cone 15 mm female according to ISO 5356-1	Same
Device Connector	11.5 mm female connector (ID) according to ISO 5356-1	15 mm male (OD)/11.5 mm (ID) female connector according to ISO 5356-1	Same

Substantial Equivalence Discussion	Subject of Submission	Primary Predicate Device	Comments
Product Name	MP02280	REF RT265	-
Length Inspiratory Line Expiratory Limb Humidifier Connection	 1.70 m ±10% (66,9 inch ±10%), including 40 cm (15.74 in) hose extension 1.63 m ± 80 mm (64.17 ±3.15 inch) 0.50 m ± 40 mm (19.7 ±1.58 inch)	 1.60 m (59 inch), including 40 cm (15.74 in) hose extension 1.60 m (63 inch) 0.70 m (27.6 inch)	Different
Resistance Inspiratory: Expiratory: 	 at 2.5 L/min < 0.1 mbar at 5 L/min < 0.2 mbar at 15 L/min < 1.0 mbar at 30 L/min < 3.0 mbar at 2.5 L/min < 0.1 mbar at 5 L/min < 0.2 mbar at 15 L/min < 0.7 mbar at 30 L/min < 2.4 mbar	 at 2.5 L/min < 0.1 mbar at 5 L/min < 0.4 mbar at 15 L/min < 1.3 mbar at 30 L/min < 9.6 mbar at 2.5 L/min < 0.1 mbar at 5 L/min < 0.2 mbar at 15 L/min < 1.4 mbar at 30 L/min < 5.3 mbar	Different
Compliance	at 60 mbar (breathing circuit: inspiration and expiration) < 0.8 mL/hPa (mL/mbar)	1.27 mL/mbar (1.3 cmH_2O)	Different
Leakage	at 20 mbar < 15 mL/min at 40 mbar < 30 mL/min at 60 mbar < 30 mL/min	@ 60 mbar ≤ 75 mL/min	Different
Volume of breathing circuit/ humidifier chamber	Inspiratory volume of the breathing circuit with incubator extension 360 ml ±10% Volume (air) of humidifier chamber with water 210 ml ±10% Volume (air) of humidifier chamber without water 300 ml ±10%	Inspiratory volume of the breathing circuit with incubator extension 450 ml Volume (air) of humidifier chamber with water 190 ml Volume (air) of humidifier chamber without water 350 ml	Different
Warm up Time	30 min	30 min	Same

Substantial Equivalence Discussion	Subject of Submission	Primary Predicate Device	Comments
Product Name	MP02280	REF RT265	-
Humidification Output	Invasive ventilation at 2 to 60 L/min > 33 mg/L Non-invasive ventilation at 2 to 60 L/min > 12 mg/L	Invasive ventilation up to 60 L/min > 33 mg/L Non-invasive ventilation up to 120 L/min > 10 mg/L	Same Different
Breathing gas temperature at Y-Piece	Adjusted and controlled by Fisher & Paykel MR850 humidifier	Adjusted and controlled by Fisher & Paykel MR850 humidifier	Same
Electrical Connection Data	22 V, 2,73 A, 60 W 14 Ω inspiratory 12 Ω expiratory (MP02650)	22 VAC, 2.73 A, 60 W, 50/60 Hz	Same
Ventilation modes	VentStar Helix dual heated (N) Plus is suitable for standard ventilation modes, such as Synchronized Intermittend Mandatory Ventilation (SIMV), Mandatory Minute Ventilation (MMV), and Continuous Positive Airway Pressure (CPAP) as well as for High Frequency Oscillation (HFO).	No information is provided in the IFU, suitable for delivery of breathing gas.	Similar

Table 2: Comparison Table VentStar Helix heated (N) Plus (MP02608)

Substantial Equivalence Discussion	Subject of Submission	Reference Predicate Device	Comments
Product Name	MP02608	MP00308	-
510(k) Number	K222822	K102618	-
Indications for use	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.	VentStar heated (N) (MP00308): Disposable inspiratory heated breathing circuit for connection to a Fisher & Paykel MR850 humidifier, for conveying moistened breathing gas between the humidifier and neonatal patients with a body weight of up to 5 kg (11 lbs).	Similar

Substantial Equivalence Discussion	Subject of Submission	Reference Predicate Device	Comments
Product Name	MP02608	MP00308	-
Description	Single-heated breathing circuits with humidifier chamber	Single-heated breathing circuits with humidifier chamber	Same
Heater	For connection to a Fisher & Paykel humidifier MR850	For connection to a Fisher & Paykel humidifier MR850	Same
Patient Population	Neonatal patients	Neonatal patients	Same
Application	Disposable	Disposable	Same
Hose diameter (Inner Diameter)	11 mm ID	Heated hose: 14 mm ID Non-heated hose: 10 mm ID	Different
Color	Inspiratory limb: blue spiral on colorless hose Expiratory limb: white spiral on colorless hose with water trap	Inspiratory limb: transparent with white heating wire inside the limp Expiratory limb: transparent	Different
Heating Wire	Inspiratory limb: in the wall of the circuit Expiratory limb: none	Inspiratory limb: white heating wire inside the limp Expiratory limb: none	Different
Connectors	ISO 5356-1 Conical Connectors	ISO 5356-1 Conical Connectors	Same
Patient Connector	Y-piece with ISO cone 15 mm female according to ISO 5356-1	Y-piece with ISO cone 15 mm female according to ISO 5356-1	Same
Device Connector	11.5 mm female (ID) connector according to ISO 5356-1	15 mm male (OD)/11.5 mm female (ID) connector according to ISO 5356-1	Same
Length Inspiratory Line Expiratory Limb Humidifier Connection	 1.70 m ±10% (66,9 inch ±10%), including 40 cm (15.74 in) hose extension 1.40 m ± 90 mm (55 ±3.54 inch) 0.50 m ± 40 mm (19.7 ±1.58 inch)	 1.2 m ±10% (47 inch ±10%) including 30 cm (11.81 inch ±10%) hose extension 1.1 m ± 60 mm (43,30 ±2.36 inch) 0.3 m ± 10 mm (11.81 ±0.39 inch)	Different

Substantial Equivalence Discussion	Subject of Submission	Reference Predicate Device	Comments
Product Name	MP02608	MP00308	-
Resistance Inspiratory: Expiratory:	 at 2.5 L/min < 0.1 mbar at 5 L/min < 0.2 mbar at 15 L/min < 1.0 mbar at 30 L/min < 3.0 mbar at 2.5 L/min < 0.1 mbar at 5 L/min < 0.2 mbar at 15 L/min < 1.0 mbar at 30 L/min < 3.3 mbar	 at 2.5 L/min < 0.1 mbar at 5 L/min < 0.4 mbar at 15 L/min < 2 mbar at 30 L/min < 7 mbar at 2.5 L/min < 0.1 mbar at 5 L/min < 0.2 mbar at 15 L/min < 1.5 mbar at 30 L/min < 5 mbar	Different
Compliance	at 60 mbar (breathing circuit: inspiration and expiration) < 1.0 mL/hPa	at 60 mbar <0.9 mL/mbar	Similar
Leakage	at 20 mbar < 15 mL/min at 40 mbar < 30 mL/min at 60 mbar < 30 mL/min	 at 60 mbar <50 mL/min	Different
Volume of breathing circuit/ humidifier chamber	Inspiratory volume of the breathing circuit with incubator extension 360 ml ±10% Volume (air) of humidifier chamber with water 210 ml ±10% Volume (air) of humidifier chamber without water 300 ml ±10%	Inspiratory volume of the breathing circuit with incubator extension 350 ml Volume (air) of humidifier chamber with water 190 ml Volume (air) of humidifier chamber without water 300 ml	Similar
Warm up Time	30 min	30 min	Same
Humidification Output	Invasive ventilation at 2 to 60 L/min > 33 mg/L Non-invasive ventilation at 2 to 60 L/min > 12 mg/L	Invasive ventilation at 4 to 30 L/min >33 mg/L Non-invasive ventilation at 4 to 30 L/min > 12 mg/L	Different
Breathing gas temperature at Y-Piece	Adjusted and controlled by Fisher & Paykel MR850 humidifier	Adjusted and controlled by Fisher & Paykel MR850 humidifier	Same

Substantial Equivalence Discussion	Subject of Submission	Reference Predicate Device	Comments
Product Name	MP02608	MP00308	-
Electrical Connection Data	22 V, 2,73 A, 60 W 14 Ω inspiratory	22 V, 2.73 A, 60 W, 16 Ω inspiratory	Same
Ventilation modes	VentStar Helix dual heated (N) Plus is suitable for standard ventilation modes, such as Synchronized Intermittend Mandatory Ventilation (SIMV), Mandatory Minute Ventilation (MMV), and Continuous Positive Airway Pressure (CPAP) as well as for High Frequency Oscillation (HFO).	Suitable for standard ventilation modes, such as Synchronized Intermittend Mandatory Ventilation (SIMV), Mandatory Minute Ventilation (MMV), and Continuous Positive Airway Pressure (CPAP) as well as for High Frequency Oscillation (HFO).	Same

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

As demonstrated in the nonclinical testing the different technological characteristics do not raise any new questions of safety and effectiveness when compared to the predicate devices.

Performance Data

Non-clinical testing of the breathing circuits has been 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. High level summary reports included in this 510(k) demonstrate that the subject devices are substantially equivalent to the predicate device.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted for VentStar Helix Dual Heated N Exten. Kit and VentStar Helix heated (N) Plus. 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 Helix Dual Heated N Exten. Kit and VentStar Helix heated (N) Plus were tested and meet all applicable requirements of the following standards:

- ISO 5367: Anaesthetic and respiratory equipment -- Breathing sets and connectors
- ISO 80601-2-12: Medical electrical equipment. Particular requirements for basic safety and essential performance of critical care ventilators
- ISO 5356-1: Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets
- ISO 80601-2-74: Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment (Gap Analysis)

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
- Extracting according to ISO 10993-18 (Exhaustive extraction in Water, Isopropanol; simulated use extraction with Isopropanol)
- 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 4.0 2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-8 09/17/2018
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	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	19-4 07/09/2014
ISO 80601-2-12 First Edition 2011	Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators [Including: Technical Corrigendum 1 (2011)]	1-98 01/30/2014
ISO 80601-2-74 First Edition 2017	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment	1-138 01/14/2019
IEC 60601-1-6 Edition 3.1 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-89 06/27/2016
IEC 62366-1 Edition 1.0 2015	Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	5-114 12/23/2016
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 2019I	Medical devices - Application of risk management to medical devices	5-125 12/23/2019

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 and raise no new safety and effectiveness questions compared to the predicate devices.

- END -