K102618

Dräger

510(k) Summary acc. to 21 CFR 807.92

DEC 10 2010

Applicants Name and Address:

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

Manufacturer Name and Address:

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

Establishment Registration Number :

9611500

Contact Person:

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Applicants US Contact Person

Joyce Kilroy
Vice President, Processes, Quality & Regulatory

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Date submission was prepared:

2010/09/03

Device Name:

Common Usual Name:	Heated Breathing Circuits
Proprietary Name:	VentStar Heated / Infinity ID Breathing Circuit Heated
Product Code:	BTT
Classification Name:	humidifier, respiratory gas, (direct patient interface)
Regulation Number:	21 CFR 868.5450
Class:	II

Legally Marketed Devices to which Substantial Equivalence is claimed:

510(k) number	Trade name	Company
K073706 K033710 K020332 K983112	Respiratory Humidifier, Model MR850, heated system RT200, RT225, RT212	Fisher & Paykel Healthcare, Ltd.
K934140	MR290 single use humidification chamber	Fisher & Paykel Healthcare, Ltd.

Device Description:
The 510(k) comprises heated breathing gas hose systems including a humidifier chamber for the ventilation of neonatal or adult patients in Intensive Care Units. The hose systems consist of two breathing hoses (inspiratory and expiratory limb) with an additional y- piece.
Inside the inspiratory and in case of the dual heated systems also in the expiratory limb of the hose system there is a heating wire which can be connected to a Fisher & Paykel humidifier MR850 to heat up the breathing gas to minimise condensation. An expiratory limb without heating wire includes a water trap. There are additional sensor ports where the temperature sensors of the Fisher & Paykel humidifier MR850 (e.g. Fisher & Paykel 900MR868) can be placed in.

In case of the neonatal system, the hose is equipped with an incubator extension for use inside an incubator.

The Infinity ID heated breathing circuits are based on the heated breathing circuits additionally equipped with an RFID identification tag. The tag stores characteristics of the breathing hose (e.g. patient type, hose diameter, resistance and compliance values, manufacturing date and shelf life) and is automatically be readout when connected to the outlets of a ventilator device which supports this function.

Intended Use:

Device Name	Intended Use
VentStar Dual Heated / VentStar Heated	Disposable inspiratory heated breathing circuit with humidifier chamber for connection to a Fisher & Paykel MR850 humidifier, for conveying moistened breathing gas between the humidifier and adult patients with a body weight of at least 40 kg (88 lbs).
VentStar Heated (N) / VentStar Heated (N) basic	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).
Infinity ID Breathing Circuit Heated (N)	Inspiratory heated breathing circuit for connection to a Fisher & Paykel MR850 humidifier, for conveying moistened breathing gas between the humidifier and neonates with a body weight of up to 5 kg (11 lbs).Intended for single-use only. Breathing circuit with integrated transponder. The transponder serves as a carrier of product-specific data for processing by Dräger Infinity ID equipment.
Infinity ID Breathing Circuit Dual Heated / Infinity ID Breathing Circuit Heated	Heated breathing circuit for connection to a Fisher & Paykel MR850 humidifier, for conveying moistened breathing gas between the humidifier and adults with a body weight of at least 40 kg (88 lbs). Intended for single-use only. Breathing circuit with integrated transponder. The transponder serves as a carrier of product-specific data for processing by Dräger Infinity ID equipment.

Summary of Testing
The following testing has been performed on the breathing systems:

- Electrical and thermal safety
- Inspiratory and expiratory limb performance
- System Compatibility with Dräger ventilators and humidifier MR850
- Materials
    - All materials used have been evaluated acc. to tests outlined in ISO 10993-1

Conclusion:
The intended use and general construction as the predicate devices remain the same.
The design of the heated breathing circuits is identical in fit, form and function to marketed products named in the table above.

It has been shown that product performance is given within the range the device can be used by clinicians.
The technological characteristics and the results of the performance data demonstrated that the heated breathing hoses issued no new risks during design verification and validation which could question device use.
In accordance with the Federal Food and Cosmetic Act and 21 CFR Part 807, based on the information provided in this premarket notification Dräger Medical AG & Co. KG concludes that the heated breathing circuits are safe, effective and substantially equivalent to the predicate devices as described in this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Draeger Medical AG & Company KG
C/O Ms. Joyce Kilroy
Draeger Medical System, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

DEC 10 2010

Re: K102618
Trade/Device Name: VentStar Heated / Infinity ID Breathing Circuit Heated
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: September 3, 2010
Received: September 13, 2010

Dear Ms. Kilroy:

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. 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.

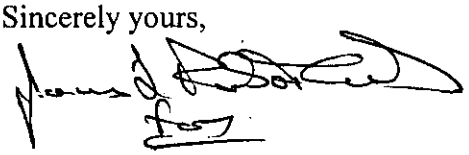
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC 10 2010

510(k) Number: K102618

Device Name: *VentStar Heated / Infinity ID Breathing Circuit Heated*

Indications for Use:

VentStar Dual Heated / VentStar Heated

Disposable inspiratory heated breathing circuit with humidifier chamber for connection to a Fisher & Paykel MR850 humidifier, for conveying moistened breathing gas between the humidifier and adult patients with a body weight of at least 40 kg (88 lbs).

VentStar Heated (N) / VentStar Heated (N) basic

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).

Infinity ID Breathing Circuit Heated (N)

Inspiratory heated breathing circuit for connection to a Fisher & Paykel MR850 humidifier, for conveying moistened breathing gas between the humidifier and neonates with a body weight of up to 5 kg (11 lbs).Intended for single-use only. Breathing circuit with integrated transponder. The transponder serves as a carrier of product-specific data for processing by Dräger Infinity ID equipment.

Infinity ID Breathing Circuit Dual Heated / Infinity ID Breathing Circuit Heated

Heated breathing circuit for connection to a Fisher & Paykel MR850 humidifier, for conveying moistened breathing gas between the humidifier and adults with a body weight of at least 40 kg (88 lbs). Intended for single-use only. Breathing circuit with integrated transponder. The transponder serves as a carrier of product-specific data for processing by Dräger Infinity ID equipment.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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