510(k) Summary (Section 5)

APR - 7 2008

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:

Dr. Karin Luebbers
Senior Manager Regulatory Affairs

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Applicants US Contact Person

Ms. Kathy Anderson
Sr. Director Regulatory Affairs

Tel. No.: (215) 660-2078
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Date submission was prepared:

2007-10-05

Device Name:

Common Name:	**Carina**
Classification Name:	Continuous Ventilator, CBK
Regulation Number:	21 CFR 868.5895
Class:	II

Legally Marketed Device to which Substantial Equivalence is claimed:

510(k) number	Trade name	Company
K984056	LTV 1000	PulmoneticSystems
K060705	Carina Home	Dräger Medical b.v.
K982454	BiPAP Vision	Respironisc

Device Description:

The Carina. is a mechanical ventilator for use inside a hospital (sub-acute care). It offers the following ventilation modes:

- VC-SIMV (Volume controlled synchronized intermittent mandatory ventilation)
- PC-AC (Pressure controlled assisted control)
- PC-SIMV (Pressure controlled synchronized intermittent mandatory ventilation)
- SPN-PS (VG) (Pressure Support + (volume guarantee))
- SPN-CPAP (Continuous Positive Airway Pressure)
- Apnoea ventilation in SPN group mode (for spontaneously breathing patients)

The device can be used for invasive and non invasive ventilation (e.g. trachea tube and mask ventilation). The device offers both high pressure oxygen inlet and oxygen via a low pressure oxygen inlet (max. 500 hPa/10L/min).

The device monitors the following ventilation parameters:

- Airway pressure (PIP, Pmean, PEEP)
- Inspiratory Tidal volume (VTi)
- Breath rate (f)
- Minutes volume (MV , MV leak)

The device has the following user-settable alarms:

- Airway pressure high
- Minute volume high / low
- Rapid shallow breathing (high frequency alarm)
- Apnea alarm
- Disconnection alarm

Flow and pressure curves are displayed on the display. Spontaneous breathing (Triggered breath)
of a patient is indicated on the screen by an asterisk (*).
Airway pressure high as a dotted line is displayed on the screen.

Intended Use:

Carina

– long-term ventilator for ventilator-dependent patients or ventilator-assisted patients

– For treatment of sub-acute care patients in hospital or medical rooms
– For invasive ventilation or non-invasive ventilation
– For patients with a tidal volume of at least100 mL
– For use by qualified medical personnel

Substantial Equivalence:

The intended use of the ventilator is comparable to the referenced predicate devices.

The comparison of the data shows similar values for the key performance data. Proposed device shows similar operating principle, ventilations mode, values for ventilator performance data and integrate monitoring functionality when compared to the legally marked devices.

In summary Dräger Medical AG & Co. KG has demonstrated that the proposed devices are safe and effective. They are considered to be substantially equivalent to currently marketed predicate devices which have been previously cleared by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2008

Draeger Medical AG & Company KG
C/O Ms. Kathy Anderson
Senior Director Regulatory Affairs
Draeger Medical System, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K072885
Trade/Device Name: Carina™
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: March 25, 2008
Received: March 28, 2008

Dear Ms. Anderson

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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

510(k) Number (if known):

Device Name: **Carina™**

Indications For Use:

The Carina is a long-term ventilator for ventilator-dependent patients or ventilator-assisted patients. The device is intended for treatment of sub-acute care patients in hospital or medical rooms. The device is intended for invasive ventilation or non-invasive ventilation. The device is intended for patients with a tidal volume of at least 100 mL. The device is intended for use by qualified medical personnel.

Federal law restricts this device to sale by or on the order of a physician.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K072885