K060705

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510(k) Summary
acc. to 807.92

JUN 14 2006

Submitter's Name and Address:
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Ms Monica Ferrante
Director, Regulatory Affairs

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Date submission was prepared: 2006-03-10

Device Name:

Common Name:	Ventilator
Classification Name:	Ventilator, Continuous
Regulation Number:	21 CRF 868.5895
Class:	II

Legally Marketed Device Identification: Carina *home*

Device Description:

the Carina home is a pressure controlled and volume controlled (pressure regulated) ventilator. The device is intended for use with patients with a tidal volume of 100 mL upwards. It is used for patients with respiratory insufficiency, using room air (also with additional oxygen).

Intended Use:

The Intended use of the Carina *home* is round-the-clock pressure controlled and pressure regulated volume controlled ventilation of patients with respiratory insufficiency, using room air, also with additional oxygen. The Carina *home* is intended for use by people without medical qualifications (patients and caregivers) as well as qualified medical and technical personnel. The device is intended for use with patients with a tidal volume of 100 mL upwards. It can be used invasive and non-invasive, for both controlled and assisted ventilation. The device can be used in Home Care environments, in and out of hospital, in stationary position (lying or sitting) or in a vehicle (e.g. car).

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Predicate Devices:

510(k) Number	Device Name
K052554	iVent 201 Portable Ventilator
K040790	LTV 1000 Ventilator
K033008	Air Safety HEPA and non-HEPA Filters
K003068	Savina
K970839	Siemens Servo Ventilator 300A

Substantial Equivalence:

The Carina home is similar to the homecare features to he iVent 201 (K052554) and the LTV 1000 (K040790).

It incorporates a pressure regulated volume controlled ventilation mode like the PRCV mode of the Siemens Servo Ventilator 300A (K970839).

It uses an integrated HEPA filter similar to HEPA filters from Air Safety Limited (K033008).

The Carina home and the iVent 201 are both software controlled ventilators using the same operating principle and can be used for invasive as well as non invasive ventilation.

The performance data of both ventilators is comparable, with the exception of some parameters. However, for these parameters, performance data is comparable with the LTV 1000 ventilator (K040790)

Summary of Performance Testing:

Safety testing was conducted per IEC60601-1, IEC60601-1-2, ASTM F1246 and other applicable standards with respect to mechanical, electrical and biocompatibility.

The results of all verification and validation testing demonstrate that all system and design requirements for the Carina home device have been met.

Qualification included hazard analysis, system level qualification and verification / validation tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2006

Dräger Medical, B.V.
C/O Ms. Monica Ferrante
Director, Regulatory Affairs
Dräger Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K060705
Trade/Device Name: Carina™Home
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: March 10, 2006
Received: March 16, 2006

Dear Ms. Ferrante:

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 STATEMENT

Indications for Use

510(k) Number (if known): _____

Device Name: **Carina™*home***

Indications for Use:

the Carina *home* is a pressure controlled and volume controlled (pressure regulated) ventilator. The device is intended for use with patients with a tidal volume of 100 mL upwards. It is used for patients with respiratory insufficiency, using room air (also with additional oxygen). Federal law restricts this device to sale by or on the order of a physician.

Sign-Off)
of Anesthesiology, General Hospital,
Control, Dental Devices
Number: K060705

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)