K082600 page 1 of 2

Dräger medical
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NOV 2 6 2008

510(k) Summary (Section 5)

acc. to 807.92

Applicant's Name and Address:
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Applicants US Contact Person:
Ms. Joyce Kilroy
Vice President Processes, Quality and Regulatory

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Date submission was prepared: 2008-09-02

Device Name:

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

Legally Marketed Device Identification: Oxylog 2000 *plus*

Device Description:

The Oxylog 2000 *plus* is a time-cycled, volume controlled emergency and transport ventilator with pressure support for patients requiring mandatory or assisted ventilation with a tidal volume from 100 mL upwards. The device is intended for use by and under the supervision of trained healthcare professionals. The device is intended for use in the following environments:

- Mobile use for emergency patients, in both outdoor and indoor environments;
- During transport in ambulances or aircraft, including helicopters;
- In accident and emergency departments;
- When moving ventilated patients around the hospital;
- In the recovery room.

Legally marketed devices to which substantial equivalence is claimed:

510(k) Number	Device Name
K984577	Oxylog 2000
K062267	Oxylog 3000

Substantial Equivalence:

The Oxylog 2000 *plus* is found substantially equivalent to the Oxylog 3000 (K062267). For those asepcts where the devices differ, the Oxylog 2000 *plus* is found substantially equivalent to the Oxylog 2000 (K984577).

Summary of Performance Testing:

Safety testing was conducted per IEC60601-1, IEC60601-1-2 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 Oxylog 2000 *plus* 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

NOV 2 6 2008

Dräger Medical, B.V.
C/O Ms. Joyce Kilroy
Vice President Processes, Quality and Regulatory
Dräger Medical Systems, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K082600
Trade/Device Name: Oxylog 2000 Plus
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: September 2, 2008
Received: September 10, 2008

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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): K082600

Device Name: Oxylog 2000 plus

Indications For Use:

The Oxylog 2000 plus is a time-cycled, volume controlled emergency and transport ventilator with pressure support for patients requiring mandatory or assisted ventilation with a tidal volume from 100 mL upwards.

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)

K082600

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

510(k) Number: K082600