510(k) Summary according to 21 CFR 807.92

OCT - 6 2011

Applicant's Name and Address:

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Applicant's US Contact Person:

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Date submission was prepared:

August 24, 2011

Device Name:

Trade Name: Oxylog 3000 plus
Common Name: Ventilator

Classification:

Class II

Regulation No.	Device	Product Code
Preferred Code Oxylog 3000 plus:		
868.5895	Ventilator, continuous,	CBK
Code for predicates (Oxylog 3000, Oxylog 2000 plus and Oxalog 2000::		
868.5895	Ventilator, continuous,	CBK

Reason for the 510(k): Substantial Equivalence:

The new Oxylog 3000 plus has been compared to the following 3 predicative devices: the Oxylog 2000 plus (K082600), the Oxylog 3000 (K062267) and the Oxylog 2000 (K984577).

All 4 devices are intended to be used for patients for emergency and transport.
All devices contain the equivalent set of ventilation modes and follow the same use philosophy.
The variations between the labeling are minimal due to the evolving development changes from the early 1990s until today.
The Oxylog 3000 plus and Oxylog 3000 (K062267) are intended for patients with a tidal volume from 50 mL upwards. Oxylog 2000 (K984577) plus and Oxylog 2000 plus (K082600) are intended for patients with a tidal volume from 100 mL upwards.

Drawn from all information presented in this submission it is summarized that Oxylog 3000 plus is as safe, as effective, and performs as well as or better than the predicate devices.

Legally Marketed Device to which Substantial Equivalence is claimed:

510(k) number	Trade name	Company
K984577	Oxylog 2000	Draeger Medical GmbH
K062267	Oxylog 3000	
K082600	Oxylog 2000 plus	

Executive Summary

This documentation covers the Oxylog 3000 plus, a new device of the Oxylog family of emergency and transport ventilators.

The Oxylog 3000 plus is intended as successor of the current Oxylog 3000. The ventilator is based on the existing Oxylog 3000 and Oxylog 2000 plus with slight adaptations like different software and a different front panel to enable the new functionality AutoFlow and CO_2 measurement in the device.

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 3000 plus have been met. Qualification included hazard analysis, system level qualification and verification / validation testing.

Device Description:

Indications for Use

The Oxylog 3000 plus is a time-cycled, volume controlled and pressure controlled emergency and transport ventilator for patients requiring mandatory or assisted ventilation with a tidal volume from 50 mL upwards.

Intended operator
The device is intended for use by and under the supervision of trained healthcare professionals, e.g. doctors, nurses, emergency medical technicians, respiratory therapists, and paramedics.

Enviroment of use

Intended environment of use:
– 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.

The following ventilation modes are offered:
•VC-CMV / VC-AC:
oVolume Controlled — Controlled Mandatory Ventilation with or without PEEP
oVolume Controlled — Assist Control with or without PEEP
•VC-SIMV: Volume Controlled — Synchronized Intermittent Mandatory Ventilation
•PC- BIPAP: Pressure Controlled- Biphasic Positive Airway Pressure
•PC- SIMV+: Pressure Controlled- Synchronized Intermittent Mandatory Ventilation
•Spn-CPAP: Spontaneous breathing- Continuous Positive Airway Pressure

Additional settings for ventilation:
•Pressure support can be supplied in the ventilation modes VC-SIMV, PC-BIPAP, Spn-CPAP.
•Apnoea ventilation for spontaneously breathing patients: in the ventilation mode Spn-CPAP.
•AutoFlow (optional): in the ventilation modes VC-CMV, VC-AC and VC-SIMV.
•NIV: in the ventilation modes: Spn-CPAP (/PS), PC-BIPAP (/PS), VC-CMV / AF, VC-AC / AF and VC-SIMV / AF. Using the NIV mode, non-intubated patients can be ventilated with a mask.

The Oxylog 3000 plus can be used as a stand alone unit or in a carrying system. This system protects the device and provides space for an O_2 cylinder. The bags of the carrying system can be used to store accessories like a ventilation hose or mask. The carrying system can be used in ambulances and hospitals. It can be mounted by means of an universal wall holder.

List of performance testing:

Performance was tested in compliance with following standards:

IEC 60601-1 :2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 : 2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
ISO 10651-3: 1997	Lung ventilators for medical use – Part 3: Particular Requirements for emergency and transport ventilators
IEC 60601-1-6 : 2004	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard - Usability
IEC 60601-1-8: 2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
ISO 14971: 2007	Medical devices - Application of risk management to medical devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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OCT - 6 2011

Re: K103625
Trade/Device Name: Oxylog 3000 plus
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK, BTL
Dated: September 30, 2011
Received: October 3, 2011

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

510(k) Number (if known): K103625

Device Name: Oxylog 3000 plus

Indications for Use:

The Oxylog 3000 plus is a time-cycled, volume controlled and pressure controlled emergency and transport ventilator for patients requiring mandatory or assisted ventilation with a tidal volume from 50 mL upwards.

Prescription Use ___X____ (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

510(k) Number: K103625