K984577

JAN 22 1999

file: 510kstate.RTF
Date: Nov,1998
Author: Frank Clanzett

510(k) SUMMARY
Summary of Safety and Effectiveness

APPLICANTS NAME AND ADDRESS:
Drager Inc.
Critical Care Systems
3136 Quarry Road
Telford , PA 18969

APPLICANTS TELEPHONE NUMBER:
(215)-721-6917

APPLICANTS FACSIMILE NUMBER:
(215)-721-6915

APPLICANTS CONTACT PERSON:
Harald Kneuer

DATE THE SUMMARY WAS PREPARED:
October 1998

DEVICE NAME:
Common Name: Oxylog 2000
Classification Name: Ventilator, Continuous
(per 21 CFR 868.5895)

LEGALLY MARKETED DEVICE TO WHICH DRÄGER IS CLAIMING SUBSTANTIAL EQUIVALENCE:
Oxylog 2000 - Manufactured by Dräger Medizintechnik GmbH, Lübeck, Germany and sold in the United States by Dräger, Inc..

DESCRIPTION OF THE DEVICE:

The device is a software controlled and time cycled transport and emergency ventilator. It can be equipped with an external power supply for stationary operation in hospitals and is equipped with a NiCd Battery Pack for the during transport. The Oxylog 2000 has 5 rotary knobs for the adjustment of the ventilator rate, tidal volume, I:E ratio, inspiratory pressure limitation and peep.

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INTENDED USE OF THE OXYLOG 2000

The Oxylog 2000 is a time cycled, volume constant transport and emergency ventilator for patients with tidal volumes starting at 100 mL.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE:

The Oxylog 2000 with the enhanced software version has exactly the same intended use like the predicate device.
The sw-change was carried out in accordance with Dräger's internal design control procedure and no questions regarding safety and effectiveness arose during this procedure.
The technology to achieve the additional monitoring function and ventilation mode is the same as already used with the predecessor. The control mechanism, the energy type and the materials used are exactly the same. The ventilator functions of the Oxylog 2000 under review were compared to the function of its predecessor. It was shown in laboratory tests that the breathing modes and the possibilities of the breathing modes are substantial equivalent.

The monitoring and alarm functions of the device under review are also comparable with the alarm and monitoring functions of the Oxylog 2000 predecessor. There were no elementary deviation between the different possibilities of the monitoring and alarm functions. The Oxylog 2000 under review is equipped with the same alarm functions as the predicate device

The device fulfils the same standards as the predecessor.

Therefore the device under review is substantially equivalent to the predicate device concerning safety, efficiency and intended use.

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Frank Clanzett
Regulatory Affairs
Dräger Medizintechnik

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 1999

Mr. Harald Kneuer
Drager, Inc.
3136 Quarry Road
Telford, PA 18969

Re: K984577
Drager Oxylog 2000
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: January 7, 1999
Received: January 11, 1999

Dear Mr. Kneuer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement for the Oxylog 2000 with the Software version 3.n

The Oxylog 2000 is a time cycled, volume constant transport and emergency ventilator for patients with tidal volumes starting at 100 mL.

With applications in:

- mobile emergency and primary care of emergency patients
- patient transports in emergency rescue vehicles or by helicopter
- patient transfers by road or air
- inner hospital transport of ventilated patients
- emergency room
- secondary transports between hospitals

Joachim Schroeter
Project Manager

12/03/1998
Date

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984577