DEC 7 1998

K983219

Dräger

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

510(k) SUMMARY
Summary of Safety and Effectiveness

APLICANTS NAME AND ADDRESS:
Drager Medizintechnik GmbH
Moislinger Allee 53-55
23542 Luebeck, Germany

APPLICANTS PHONE NUMBER:
49-451-882-3915

APPLICANTS FAX NUMBER:
49-451-882-4351

APPLICANTS CONTACT PERSON:
Frank Clanzett
Regulatory Affairs Specialist

DATE THE SUMMARY WAS PREPARED:
August, 1998

DEVICE NAME:

Common Name:	Evita 4 NeoFlow™
Classification Name:	Ventilator, Continuous (per 21 CFR 868.5895)

LEGALLY MARKETED DEVICE TO WHICH DRÄGER IS CLAIMING SUBSTANTIAL EQUIVALENCE:

Evita 4 - Manufactured by Dräger Medizintechnik GmbH, Lübeck, Germany and sold in the United States by Dräger, Inc.

Babylog 8000 plus- Manufactured by Dräger Medizintechnik GmbH, Lübeck, Germany and sold in the United States by Dräger, Inc.

Servo 300 - Sold in the United States by Siemens

Dräger

DESCRIPTION OF THE DEVICE:

The Evita 4 NeoFlow option extends the patient range of the Evita 4 ventilator to neonates with a minimum weight of 0,5 kg.

The Evita 4 equipped with the NeoFlow option provides the following ventilation modes.

- CMV/assist — Controlled Mandatory Ventilation
  Controlled and assisted volume contant ventilation with the options:
  - CPV — Continuous Positive Pressure Ventilation
  - PLV — Pressure Limited Ventilation
  - AutoFlow — For automatic regulation of inspiratory flow
  - IRV — Inversed Ratio Ventilation
- SIMV — Synchronized Intermittent Mandatory Ventilation
  Procedure for weaning patients off the ventilator after they have started spontaneous breathing. With the options:
  - PLV
  - AutoFlow
- MMV — Mandatory Minute Volume Ventilation
  Spontaneous breathing with automatic adjustment of mandatory ventilation to the patients minute volume requirement. With the options:
  - PLV
  - AutoFlow
- SB — Spontaneous Breathing
  Spontaneous breathing at ambient pressure
- CPAP — Continuous Positive Airway Pressure
  Spontaneous breathing with positive airway pressure
- ASB/PSV — Assisted Spontaneous Breathing / Pressure Support Ventilation
  Pressure supported spontaneous breathing
- PCV+ — Pressure Controlled Ventilation
  Pressure controlled ventilation combined with free spontaneous breathing during the complete breathing cycle, and adjustable pressure increase to CPAP level
- APRV — Airway Pressure Release Ventilation
  Spontaneous breathing on two pressure levels with long time ranges - independently adjustable
- Apnea Ventilation — For switching over automatically to volume controlled mandatory ventilation if breathing stops
- ILV — Independent Lung Ventilation
  Separate, differentiated, synchronized ventilation with one Evita 4 for each lung.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 7 1998

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

Re: K983219
Neoflow Option for Evita 4 and Evita 2 Dura Ventilators
Regulatory Class: II (two)
Product Code: CBK
Dated: September 11, 1998
Received: September 14, 1998

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 Drager Evita 4 / 2 Dura NeoFlow Option:

NeoFlow – Neonatal mode with base flow.

The Evita 4 / 2 Dura with NeoFlow Option is a long-term ventilator to be used for intensive care and inner clinical transport of adults, children, infants and neonates with a minimum body weight of 0.5 kg.

The device is microprocessor controlled and provides the following ventilation modes:

- **CMV/assist** Controlled Mandatory Ventilation
  Controlled and assisted volume constant ventilation, with the options:
  - CPPV Continuous Positive Pressure Ventilation
  - PLV Pressure Limited Ventilation
  - AutoFlow For automatic regulation of inspiratory flow
  - IRV Inversed Ratio Ventilation

- **SIMV** Synchronised Intermittent Mandatory Ventilation
  Procedure for weaning patients off the ventilator after they have started spontaneous breathing. With the options:
  - PLV
  - AutoFlow

- **MMV** Mandatory Minute Volume Ventilation
  Spontaneous breathing with automatic adjustment of mandatory ventilation to the patients minute volume requirement. With the options:
  - PLV
  - AutoFlow

- **SB** Spontaneous Breathing
  Spontaneous breathing at ambient pressure

- **CPAP** Continuos Positive Airway Pressure
  Spontaneous breathing with positive airway pressure

- **ASB/PSV** Assisted Spontaneous Breathing / Pressure Support Ventilation
  Pressure supported spontaneous breathing

- **PCV+** Pressure controlled ventilation, combined with free spontaneous breathing during the complete breathing cycle, and adjustable pressure increase to CPAP level

- **APRV** Airway Pressure Release Ventilation
  Spontaneous breathing on two pressure levels with long time ranges - independently adjustable.

- **Apnea Ventilation** For switching over automatically to volume controlled ventilation if breathing stops.

- **ILV** Independent Lung Ventilation
  Separate, differentiated synchronised ventilation with one Evita 4 / 2 Dura for each lung.

Mark Kramer
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983219

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