K083050
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510(k) Summary acc. to 21 CFR 807.92

Applicants Name and Address:

DEC 29 2008

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

Manufacturer Name and Address:

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

Establishment Registration Number :

9611500

Contact Person:

Ulrich Schroeder
Head of Regulatory & Clinical Affairs

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Applicants US Contact Person

Joyce Kilroy
Vice President, Processes, Quality & Regulatory

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Fax No.: (215) 721-5424

Date submission was prepared:

10/10/2008

Device Name:

Common Name:	**Evita XL**
Classification Name:	Continuous Ventilator, CBK
Regulation Number:	21 CFR 868.5895
Class:	II

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Legally Marketed Devices to which Substantial Equivalence is claimed:

510(k) number	Trade name	Company
K 010093; K 980642	Evita XL	Draeger Medical AG & Co. KG
K 974176	Babylog 8000 plus	Draeger Medical AG & Co. KG

Device Description:

Evita XL is a time-cycled microprocessor-controlled intensive care ventilator intended to provide continuous ventilation for adults, children, neonates and infants with Neoflow option. The device can be also operated in the mask ventilation mode if the according option is installed. Software modification implements these new software options:

- Option Mask Ventilation Plus (NIV Plus)
- Option Inspiratory Termination Criteria (Insp. Term. PIF)
- Option Proportional Pressure Support (PPS)

NIV Plus is a supplement to the existing Mask ventilation option (NIV), which improves ventilation performance (triggering and patient comfort) through higher leakage compensation and smooth ending of Assistant Spontaneous Breathing (ASB) strokes. NIV Plus implements Standby Plus an alternative for starting the active ventilation mode in mask ventilation when the patient takes the first spontaneous breath. Anti Air Shower detects disconnection during mask ventilation if the mask is deliberately removed from the face and reduces the flow supplied for the time of the disconnection.

Insp. Term. PIF is an adjustable stop criterion for pressure support strokes. At the end of the inspiratory phase the delivered inspiratory flow falls under a certain level of the maximum inspiratory flow. The ventilator cycles from inspiration phase to expiration phase when a fixed level was reached. The software modification allows it to adjust this inspiration termination criterion. The device can be configured by the user (adjustable inspiration termination criterion or fixed value is active).

The ventilation mode Proportional Pressure Support (PPS) is a software option for the ventilator Evita XL designed to assist the spontaneous breathing patient.
In PPS, the device supports the patient's spontaneous breathing in proportion to the breathing effort. The degree of support in PPS mode can be set separately according to resistive and elastic components directly proportional to the patient effort.

Intended Use:

Long-term ventilator for intensive care.
For adults, children, and neonates with a minimum body weight of 3 kg (6.6 lbs). For premature infants with a minimum body weight
of 0.5 kg (1.1 lbs) with the NeoFlow option.

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Conclusion:

The technological characteristics of the device, the results and conclusions of the performed risk analysis, as well as the performed software validation measures and its results demonstrate that the new software options (NIV Plus; Insp. Term. PIF; PPS) for the critical care ventilator Evita XL are safe and effective and are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 2008

Dräger Medical AG & Co. KG
C/O Joyce Kilroy
Vice President, Processes, Quality & Regulatory
Draeger Medical System, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K083050
Trade/Device Name: Evita XL
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: November 28, 2008
Received: December 2, 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) 276-0120. 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 Statement

510(k) Number (if known)	K 083050
Device Name	*Evita XL*
Indications for Use	Long-term ventilator for intensive care. For adults, children, and neonates with a minimum body weight of 3 kg (6.6 lbs). For premature infants with a minimum body weight of 0.5 kg (1.1 lbs) with the NeoFlow option.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___X___ (Per 21 CFR 801. 109) OR Over-The-Counter Use_____

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

510(k) Number: K083050