Dräger medical
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FEB - 6 2008

K072412

510(k) Summary
acc. to 21 CFR 807.92

Submitter's Name and Address:
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Applicant's US Contact Person:
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Senior Director Regulatory Affairs

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Date submission was prepared: July 31st, 2007

Device Name:

Common Name:	Intensive Care Ventilator
Classification Name:	Continuous Ventilator
Regulation Number:	21 CFR 868.5895
Class:	2

Legally Marketed Device Identification: EvitaXL with SmartCare Option (K051263)

Device Description:

The EvitaXL is a time-cycled microprocessor-controlled intensive care ventilator. The option SmartCare™ for the EvitaXL has been developed for assisting physicians and respiratory therapists with the standardization of the weaning process used in intensive care units. The system uses a computerbased representation of a protocol and focusses on the management of pressure support.

Scope of this submission is an extension of claims made in the promotional material, while the device itself remains unchanged except for minor modifications that led to non-filing decisions. The indications for use, the intended use and the instructions for use also remain unchanged.

Intended Use:

The SmartCare/PS system is designed to stabilize the patient's spontaneous breathing in a "comfortable zone" and to reduce inspiratory support. SmartCare can be used for intubated or tracheotomized patients. Patients with body weight between 15 and 35 kg (33.1 and 77.8 lbs) must be endotracheally intubated and ventilated with active humidification. The patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing.

Predicate Device:

510(k) Number	Device Name	Manufacturer
K051263	EvitaXL	Dräger Medical AG & Co. KG

Substantial Equivalence:

The device and its labelling are identical to the predicate device. Substancial equivalence is claimed on that basis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dräger Medical AG & Co. KG
C/O Ms. Kathy Anderson
Senior Director, Regulatory Affairs
Draeger Medical Systems, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K072412
Trade/Device Name: EvitaXL with Option SmartCare
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: January 18, 2008
Received: January 23, 2008

Dear Ms. Anderson:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 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):

Device Name: EvitaXL with Option SmartCare

Indications For Use: The EvitaXL is a long-term ventilator for intensive care for adults, children, and infants with a body weight of at least 3 kg (6.6 lbs).

With SmartCare™/PS the EvitaXL is intended to stabilize the patient's spontaneous breathing in a "comfortable zone" and to reduce inspiratory support for adults and children with a body weight of at least 15 kg (33 lbs). The patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing. SmartCare can be used for intubated or tracheotomized patients. Patients with body weight between 15 and 35 kg (33.1 and 77.8 lbs) must be endotracheally intubated and ventilated with active humidification.

SmartCare™/PS is contraindicated in case of severe COPD and severe neurologic disorder that affects the cerebral control mechanism of the spontaneous breathing pattern.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K072412