K051263

JUL 12 2005

510(k) Summary

(Section 3)

In this section the 510(k) summary acc. to 807.92 is provided.

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510(k) Summary
acc. to 21 CFR 807.92

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Ms Monica Ferrante
Director Regulatory Affairs

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Date submission was prepared: April 15, 2005

Device Name:

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

Legally Marketed Device Identification: EvitaXL (K980642, K983219, K992608, K010093)

Device Description:

The EvitaXL is a time-cycled microprocessor-controlled intensive care ventilator. Basic difference to the predecessors Evita 2dura and Evita 4, which have been cleared by premarket notifications, is the larger graphic user interface. Both predecessors can be upgraded by means of an EvitaXL option and thus feature the identical functionality.

For the EvitaXL a new system called SmartCare™ 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 protocols and focusses on the management of pressure support.

The SmartCare / PS system refers to measured patient data and adjusts the pressure support provided by EvitaXL for intubated or tracheotomized patients. SmartCare / PS incorporates a strategy that gradually reduces the level of assistance, at a rate that is guided by a patient's tolerance, while measuring his/her capacity to breathe without mechanical assistance of the ventilator. SmartCare / PS provides the advantage of 24-hour-a-day continuous respiratory management with adaptation of the level of assistance.

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SmartCare / PS essentially uses three parameters measured by EvitaXL:
- — respiratory rate
- — tidal volume
- — expiratory CO_2 concentration

It controls the level of pressure (PSupp. above PEEP) during ventilation in CPAP/PS mode.

SmartCare / PS has three main functions:
- — automatic adaptation of ventilatory assistance
- — automatic weaning strategy
- — automation of the weaning test

In order to achieve the above-defined targets, the level of pressure support (PSupp.) is periodically adapted by SmartCare / PS, based on increasing pressure in case of tachypnea and lowering pressure in case of bradypnea and low $etCO_2$.

Physically, the SmartCare / PS system has been accomplished by adding a printed circuit board and software. This makes it possible to run the necessary calculations and analyses independently of the EvitaXL's core ventilation tasks.

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 Devices:

510(k) Number	Device Name	Manufacturer
K980642	Evita 4, Evita 2dura	Dräger Medical AG & Co. KGaA
K983219	Evita 4, Evita 2dura	Dräger Medical AG & Co. KGaA
K992608	Evita 4, Evita 2dura	Dräger Medical AG & Co. KGaA
K010093	Evita 4, Evita 2dura	Dräger Medical AG & Co. KGaA
K040574	Galileo Gold	Hamilton Medical AG
K970839	Servo[i]	Maquet Critical Care AB
K021573	840	Tyco NPB

Substantial Equivalence:

The intended use of the SmartCare / PS option for the EvitaXL intensive care ventilator is comparable to the predicate devices. All devices offer functions that use measured respiratory data to directly interact with the patient and adjust certain parameters without explicit confirmation of a medical doctor or respiratory therapist. Nevertheless, parameters that are under control of the ventilator may only be varied within a predetermined range. Additionally, monitoring functions are still in place and alarms remain active. The materials and design are also similar to those predicate devices. The technological characteristics of the SmartCare / PS system do not raise new questions regarding safety or effectiveness of the EvitaXL critical care ventilator. Furthermore, the labeling associated with SmartCare / PS provides similar information as the predicate devices.

Information provided in the 510(k) submission supports the determination of substantial equivalence. Software design, development and verification was performed in accordance with FDA guidances and company internal standards. Safety and performance testing was conducted using international, FDA recognized standards and other company internal standards as far as affected. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

016

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Effectiveness of the SmartCare protocol has sufficiently been demonstrated by means of clinical studies on human patients. Results demonstrate that the SmartCare protocol is safe and effective in comparison to current ventilator standard of care.

In summary Dräger Medical AG & Co. KGaA has demonstrated the SmartCare system to be as safe and as effective as the referenced predicate devices. The EvitaXL with the SmartCare option is considered to be substantial equivalent to currently marketed devices which have been previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2005

Drager Medical AG & Co. KGAA
c/o Ms. Monica Ferrante
Director of Regulatory Affairs
Drager Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K051263
Trade/Device Name: EvitaXL with Option SmartCare
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: April 29, 2005
Received: May 16, 2005

Dear Ms. Ferrante:

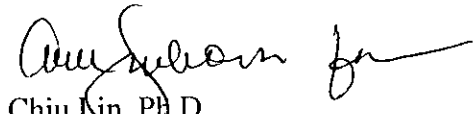
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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): K 051263

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 effects 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: K051263