

SEP 4 1998

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

510(k) SUMMARY
Summary of Safety and Effectiveness

K980642

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
Regulatory Affairs Manager

DATE THE SUMMARY WAS PREPARED:

February, 1998

DEVICE NAME:

Trade Name:	Evita 4
Common Name:	Evita 4
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.

Evita 2 dura- Manufactured by Dräger Medizintechnik GmbH, Lubeck, Germany and sold in the United States by Dräger, Inc.

Servo 300 - Sold in the United States by Siemens

DESCRIPTION OF THE DEVICE:

The Evita 4 with the Software version 3.0 is a time cycled, constant volume ventilator for long term use. 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:
 - 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.

Intensive Care Ventilator Data Comparison Sheet

Specification	Evita 4 (K 961687)	Evita 2 dura (K 970165)	Servo 300 (K902859)	Evita 4 SW 3.0
Manufacturer	Dräger	Dräger	Siemens	Dräger
Classification: Intensive Care Ventilator	Yes	Yes	Yes	Yes
Operating Principle: Time cycled , volume constant, pressure controlled	Yes	Yes	Yes	Yes
Software controlled	Yes	Yes	Yes	Yes
Contoll Software: Version 3.0	No (1.0)	Yes	NA	Yes
Gas delivery system: Fast „High Pressure Servo Valve“, microprocessor controlled	Yes	Yes	Yes	Yes
Intended Use	Evita 4 is a time cycled, constant volume, long term, intensive care ventilator for adults and children with a body weight of at least 3 kg.	like Evita 4 (K 961687)	N.A.	Evita 4 is a time cycled, constant volume, long term, intensive care ventilator for adults and children with a body weight of at least 3 kg

Dräger

Specification	Evita 4 (K 961687)	Evita 2 dura (K 970165)	Servo 300 (K902859)	Evita 4 SW 3.0
Modes of Ventilation:	-	-	-	identical with Evita 4 510(k) no: K 961687
Ventilator Settings	-	-	-	identical with Evita 4 510(k) no: K 961687
Flow Trigger Sensivity	-	-	-	identical with Evita 4 510(k) no: K 961687
Parameter setting	-	-	-	identical with Evita 4 510(k) no: K 961687
Monitors/Indicators	-	-	-	identical with Evita 4 510(k) no: K 961687
Pressure Limitation	-	-	-	identical with Evita 4 510(k) no: K 961687
Alarm Functions	-	-	-	identical with Evita 4 510(k) no: K 961687
Displayed Values	-	-	-	identical with Evita 4 510(k) no: K 961687
Displayed Curves	-	-	-	identical with Evita 4 510(k) no: K 961687

Specification	Evita 4 (K 961687)	Evita 2 dura (K 970165)	Servo 300 (K902859)	Evita 4 SW 3.0
Special Functions				
Intermittend PEEP	Yes	Yes	-	identical with Evita 2dura
Inspiration Hold	No	Yes	-	identical with Evita 2dura
Apnea Ventilation	Yes	Yes	-	identical with Evita 2dura
Nebulization	Yes	Yes	-	identical with Evita 2dura
Nebulization in pediatric mode	No	Yes	-	identical with Evita 2dura
Suction Help Mode	Yes	Yes	-	identical with Evita 2dura
Switch over function	Yes	Yes	-	identical with Evita 2dura
Leak-Compensation	No	Yes	-	identical with Evita 2dura
Minute Volume-Leak	No	Yes	-	identical with Evita 2dura
Physical Characteristics	-	-	-	identical with Evita 4 510(k) no. K 961687

INTENDED USE OF THE DEVICE

Evita 4 (SW 3.0) is a time cycled, constant volume, long term, intensive care ventilator for adults and children with a body weight of at least 3kg.

Intended Environment for the device:

- user facilities
- inner clinical transport

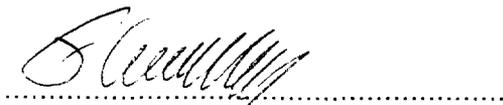
SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES:

The ventilator functions of the Evita 4 with the enhanced software version are substantially equivalent to the Evita 2 dura, the Evita 4 with the former software and the Servo 300 ventilators.

The Evita 4 with enhanced software integrates the same optional functions that are presently performed by the Evita 4 with the former software.

The device fulfils at least the same standards as the Evita 2 dura.

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



Frank Clanzett
Regulatory Affairs
Dräger Medizintechnik



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 4 1998

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

Re: K980642
Evita 4
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: June 12, 1998
Received: June 15, 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.

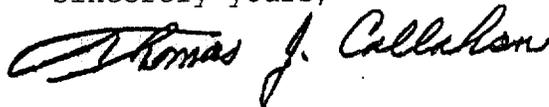
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major Regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Harald Kneuer

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

Enclosure

INTENDED USE STATEMENT OF THE EVITA 4, SW 3.0

Evita 4 is a time cycled, constant volume, long term, intensive care ventilator for adults and children with a body weight of at least 3 kg.

Intended Environment for the device:

- hospital use
- inner clinical transport



Frank Clanzet
(Regulatory Affairs)

1. September 1998



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

510(k) Number K98064Z

✓ Prescription Use