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510(k) SUMMARY
Summary of Safety and Effectiveness

APPLICANTS NAME AND ADDRESS:
Drager Inc.
Critical Care Systems
4101-100 Pleasant Valley Road
Chantilly, VA 20151

AUG 26 1997

APPLICANTS TELEPHONE NUMBER:
(703)-817-0100

APPLICANTS FACSIMILE NUMBER:
(703)-817-0101

APPLICANTS CONTACT PERSON:
Harald Kneuer
Regulatory Affairs Manager

DATE THE SUMMARY WAS PREPARED:
November 11, 1996

DEVICE NAME:

Trade Name:	Evita 2 dura
Common Name:	Evita 2 dura
Classification Name:	Ventilator, Continuous (per 21 CFR 868.5895)

LEGALLY MARKETED DEVICE TO WHICH DRAGER INC. IS CLAIMING SUBSTANTIAL EQUIVALENCE:

Evita 4 - Manufactured by Dragerwerk AG, Lubeck, Germany and sold in the United States by Drager Inc.

Evita - Manufactured by Dragerwerk AG, Lubeck, Germany and sold in the United States by Drager Inc.

Servo 300 - Sold in the United States by Siemens

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Intensive Care Ventilator Data Comparison Sheet

Device	Evita 4	*Evita 2 dura*	Evita	Servo 300
510 (K) number	K 961687		K 924930	K902859
Manufacturer	Dräger	Dräger	Dräger	Siemens
Classification	Intensive Care Ventilator	Intensive Care Ventilator	Intensive Care Ventilator	Intensive Care Ventilator
Working Principle	time cycled, volume constant, pressure controlled.	like Evita 4 like Evita 4	time cycled, volume constant, pressure controlled.	time cycled, volume constant, pressure controlled.
Software controlled	Yes	Yes	Yes	Yes
Gas delivery system	Fast "High Pressure Servo Valve", microprocessor controlled .	like Evita 4	Fast "High Pressure Servo Valve", microprocessor controlled	Fast "High Pressure Servo Valve", microprocessor controlled
Voltage for gas delivery system	12 V DC	like Evita 4	12 V DC	-

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Device	Evita 4	Evita 2 dura	Evita	Servo 300
Pneumatic Unit	Partnumber 84 12 360	like Evita 4		
Software for Pneumatic Unit	Partnumber 84 11 742	like Evita 4		
Electronic Unit	Partnumber 84 12 835	like Evita 4		
Software for Electronic Unit	Partnumber 84 11 741	like Evita 4		
Modes of Ventilation:				
CMV	Yes	Yes	Yes	Yes
SIMV	Yes	Yes	Yes	Yes
CPAP	Yes	Yes	Yes	Yes
ASB	Yes	Yes	Yes	Yes
Assist Control	Yes	Yes	Yes	Yes
MMV	Yes	Yes	Yes	No
PCV+ (BIPAP)	Yes*1	Yes*1	Yes	Yes
APRV	Yes	Yes	Yes	No
CMV, Assist Control, SIMV and MMV with AutoFlow	Yes*2	Yes*2	No	Yes
ILV	Yes	Yes	Yes	

* see explanation of differences

Device	Evita 4	*Evita 2 dura*	Evita	Servo 300
Ventilator Settings				
Rate	0.5 to 100 bpm	like Evita 4	5 to 60 bpm for CMV 0.5 to 20 bpm for SIMV	5 to 150 bpm for CMV 0.5 to 40 bpm for SIMV
Vt	0.02 to 0.3 L (Pediatric Mode)*3 0.1 to 2.0 L (Adult Mode)*3	like Evita 4	0.1 to 2.0 L	0.002 to 4.0 L
Tinsp	0.1 ... 10 s	like Evita 4	not directly adjustable	10 to 80 % (stepless)
I:E-Ratio	not directly adjustable*4	like Evita 4	4:1 to 1:5	not directly adjustable
Flow	6 to 30 lpm (Paediatric Mode)*3 6 to 120 lpm (Adult Mode)*3	like Evita 4	6 to 120 lpm	not directly adjustable
Pmax	0 to 100 cmH2O	like Evita 4	0 to 100 cmH2O	10 to 120 cmH2O
PEEP	0 to 35 cmH2O	like Evita 4	0 to 35 cmH2O	0 to 50 cmH2O
O2-Conc.	21 to 100 Vol.%	like Evita 4	21 to 100 Vol.%	21 to 100 Vol.%
Flow Trigger Sensivity				
for CMV assist	0.3 to 15 lpm*5	like Evita 4	0.5 to 5.0 cmH2O	0 to 17 cmH_2O P. trigger
for SIMV	0.3 to 15 lpm*5	like Evita 4	0.7 cmH2O fixed trigger	0 to 17 cmH_2O P. trigger
for ASB (pressure support)	0.3 to 15 lpm	like Evita 4	1 to 15 lpm	0 to 17 cmH_2O P. trigger
for CPAP	0.2 cmH2O fixed trigger	like Evita 4	0.2 cmH2O fixed trigger	
Pinsp	0 to 80 cmH2O	like Evita 4	10 to 100 cmH2O	0 to 100 cmH2O
Rise time	0 to 2 s	like Evita 4	0 to 2 s	0 to 10 %
Pressure Support	0 to 80 cmH2O	like Evita 4	0 to 80 cmH2O	0 to 100 cmH2O

* see explanation of differences

Device	Evita 4	*Evita 2 dura*	Evita	Servo 300
Parameter setting				
Main ventilation settings	with 10.4" Color TFT-LC-display, Touch screen and central	With keys, 7-Seg. Display rotary knob and central rotary dial knob for selecting and confirming*[6]	rotary knob for every parameter	rotary knob for every parameter
further settings	With 10.4" Color TFT-LC-Display, Touch screen and central rotary knob	Via menu	menu via hardkeys	-
Monitors/Indicators				
Power ON	TFT-LC-Display (Color)	LC-Display (monochrom) or TFT (Color)	LC-Display	LED
Dimension of Display	21.1cm x 15.8cm 640 x 480 dots	12.5cm x 9.5cm 640 x 480 dots	9.8cm x 7.9cm 128 x 240 dots	
Alarm Condition	red LED and TFT- LC-Display	red LED and TFT or LC-Display	red LED and LC Display	red LED and LED Display
Warnings	yellow LED and TFT-LC-Display	yellow LED and LC or TFT	yellow LED and LC-Display	
Messages	TFT-LC-Display	LCD-or TFT-Display	LC-Display	LED-Display
Curves	TFT-LC-Display	LCD-or TFT-Display	LC-Display	no

* see explanation of differences

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Device	Evita 4	Evita 2 dura	Evita	Servo 300
Measured values	TFT-LC-Display	LC-or TFT Display	LC-Display and 7-Segment-Display	several LED-Displays
Adjusted values	TFT-LC-Display	7-Segment Display and LC- or TFT- Display	Scale of potentiometer and LC-Display	Scale of potentiometer and LED-Display
Audible Alarm	Yes	Yes	Yes	Yes
Alarm sound level	adjustable	adjustable	fixed	adustable
Pressure Limitation				
adjustable Pmax	0 to 100 cmH2O	like Evita 4	0 to 100 cmH2O	10 to 100 cmH2O
Safety Valve	100 cmH2O	like Evita 4	100 cmH2O	120 cmH2O
Inspiratory relief valve	Yes	like Evita 4	Yes	Yes

* see explanation of differences

Device	Evita 4	*Evita 2 dura*	Evita	Servo 300
Alarms				
Airway Pressure High /Low	Yes	Yes	Yes	Yes
Minute volume High / Low	Yes	Yes	Yes	Yes
Apnea	Yes	Yes	Yes	Yes
Gas Supply Failure	Yes	Yes	Yes	Yes
Power failure	Yes	Yes	Yes	Yes
Alarm Silence / Reset	Yes	Yes	Yes	Yes
Ventilator Inoperative	Yes	Yes	Yes	Yes
Breathing frequency High	Yes	Yes	Yes	No
Oxygen concentration High / Low	Yes	Yes	Yes	Yes
Breathing gas temperatur High	Yes	Yes	Yes	No
Endexpiratory CO_2-concentration				
etCO2 High / Low	Yes	Yes*[8] (option)	No	No
O2 saturation SpO2 High / Low	Yes (option)*9	Yes*9	No	No
Pulse High / Low	Yes (option) *9	Yes*9	No	No

* see explanation of differences

Device	Evita	*Evita 2 dura*	Evita	Servo 300
Displayed Values				
max. airway pressure Ppeak	0 to 99 cmH$_2$O	like Evita 4	0 to 99 cmH$_2$O	Yes
Plateau pressure	0 to 99 cmH$_2$O	like Evita 4	0 to 99 cmH$_2$O	Yes
PEEP	0 to 99 cmH$_2$O	like Evita 4	0 to 99 cmH$_2$O	Yes
mean airway pressure	0 to 99 cmH$_2$O	like Evita 4	0 to 99 cmH$_2$O	Yes
min. airway pressure	0 to 99 cmH$_2$O	like Evita 4	0 to 99 cmH$_2$O	No
insp. oxygen concentration	15 to 100 Vol.-%	like Evita 4	5 to 99 Vol.-%	Yes
Minute volume MV	0 to 99 lpm	like Evita 4	0 to 99 lpm	Yes
spont. breath. volume MVspon	0 to 99 lpm	like Evita 4	0 to 99 lpm	No
Tidal volume V$_T$	0 to 3999 ml	like Evita 4	0 to 3999 ml	Yes
spont. tidal volume V$_T$spon	0 to 3999 ml	like Evita 4	0 to 3999 ml	No
breathing frequency f	0 to 150 bpm	like Evita 4	0 to 80 bpm	Yes
spont. breathing frequency f$_{spon}$	0 to 150 bpm	like Evita 4	0 to 80 bpm	No
breathing gas temperatur	18 to 51°C	like Evita 4	18 to 51°C	No
endexp. CO$_2$-concentration etCO$_2$	0 to 13.3 Vol.%	like Evita 4 *[8]	-	No

Device	Evita 4	*Evita 2 dura*	Evita	Servo 300
CO_2-production	0 to 999 ml/min	like Evita 4[*8]	-	No
Seriel dead space Vds	0 to 999 ml	like Evita 4[*8]	-	No
Dead Space Ventilation Vds/VT	0 to 999 ml	like Evita 4[*8]	-	-
etCO2	0 to 13.3 Vol%	like Evita 4[*8]	-	-
Compliance C (calculated value)	0 to 250 ml/cmH2O	like Evita 4	0 to 250 ml/cmH2O	No
Resistance R (calculated value)	0 to 99 cmH2O/l/s	like Evita 4	0 to 99 cmH2O/l/s	No
Pulse Rate	20 to 250 bpm (option*9)	like Evita 4[*9]	-	No
SpO2	0 - 100 %[*9]	like Evita 4[*9]	-	-
Displayed curves				
Airway pressure Paw (t)	Yes	like Evita 4	Yes	No
Flow (t)	Yes	like Evita 4	Yes	No
Exsp. CO2-concentration FCO2	Yes	like Evita 4[*8]	-	No
Plethmogram	Yes[*9]	like Evita 4	-	-

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Device	Evita 4	*Evita 2 dura*	Evita	Servo 300
Special Functions				
Intermittend PEEP	Yes	like Evita 4	Yes	No
Inspiration Hold	Yes	like Evita 4	Yes	Yes
Apnea Ventilation	Yes	like Evita 4	Yes	Yes
Nebulization	Yes	like Evita 4	Yes	Yes
Suction Help Mode	Yes	like Evita 4	Yes	No
Switch over function	Yes	like Evita 4	Yes	Yes
Physical Characteristics				
Dimensions WxHxD	530 x 290 x 450 mm	530 x 290 x 420 mm	530 x 270 x 420 mm	242 x 360 240 mm (pneumatics) 427 x 110 321 mm (front panel)
Weight	27 kg	like Evita 4	27 Kg	23.2 kg
Operation Temperature	10 to 40°C	like Evita 4	15 to 40°C	
Storage Temperature	-20 to 60°C	like Evita 4	-20 to 60°C	

* see explanation of differences

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Device	Evita 4	*Evita 2 dura*	Evita	Servo 300
Power Supply				
AC-Power connection range	100V to 240 V, 50/60 Hz	like Evita 4	100V to 127 V, 220 V to 240 V, 50/60 Hz	100, 120, 220 and 240 V AC, 50/60 Hz
Power consumption	approximately 125 W	like Evita 4	approximately 125 W	40 W
DC-connection	Option, range 12 or 24V DC*[10]	like Evita 4	No	24 V DC
Internal battery	Option *[10]	like Evita 4	No	Yes
Operating time with battery	> 10 min *[10]	like Evita 4	No	Approx. 30 min
Typ of internal batterie	lead, free of maintenance	like Evita 4	-	lead, free of maintenance
Recharge time	< 1.5 hours	like Evita 4	-	10 hours

* see explanation of differences

Explanation of Differences

1   Evita 2 dura and Evita 4 uses the name PCV+ instead of the name BIPAP for the same ventilation mode. This pressure controlled ventilation mode is combined with free spontaneous breathing during the complete breathing cycle.

2   Evita 2 dura and Evita 4 uses extra setting AutoFlow for all volume controlled ventilation modes (CMV, SIMV, and MMV) instead of a seperate mode (Pressure regulated volume controlled of the serve 300).

3   Evita 2 dura and Evita 4 distinguishes between an Adult and a Pediatric Mode, which can be selected by the user after switching on.

4   Evita 2 dura and Evita 4 uses instead of an I:E-adjustment the adjustment of the Inspiratory Time Tinsp

5   Evita 2 dura and Evita 4 uses the Flow Trigger for the adustment of the trigger sensivity in all ventilation modes

6   Evita 2 dura uses a different operating concept:
11 ventilation parameter, for example VT is adjusted as follows:
By pressing a key the parameter the adjusted parameter is selected. After that the yellow LED on the key is activated.
Turn the central rotary knob = adjust the value
Press the central rotary knob = confirm the value
The yelow LED is switched off.
The value is displayed by a 7-Segement-Display.

7   In Evita 2 dura for adjusting of the parameters are no potentiometer used. The adjusted value is displayed by 7-Segment-displays (each 11 parameters have an own 7-segment-display).

8   Evita 2 dura can be equipped with an built-in monitoring for the expiratory CO_2 concentration. The basic version of Evita 4 is equipped with this feature.

9   Evita 2 dura and Evita 4 can be equipped optional with an oxygen saturation measurement

10   Evita 2 dura and Evita 4 can be equipped with a DC power supply

* see explanation of differences

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DESCRIPTION OF THE DEVICE:

The Evita 2 dura is a time cycled, constant volume ventilator for long term use in intensive care and inner clinical transport. The device is microprocessor controlled and 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 2 dura for each lung

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INTENDED USE OF THE DEVICE:

The Evita 2 dura is a long term ventilator for the intensive care of patients with a body weight of at least 3 Kg up to 200 Kg.

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

- CMV	Controlled Mandatory Ventilation
- SIMV	Synchronized Intermittent Mandatory Ventilation
- MMV	Mandatory Minute Volume Ventilation
- CPAP	Continuous Positive Airway Pressure
- PCV+	Pressure Controlled Ventilation, combined with free spontaneous breathing during the complete breathing cycle and adjustable pressure support from 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 2 dura unit for each lung.

Application range - Intensive Care units
- Inner clinical transport

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

The ventilator functions of the Evita 2 dura are substantially equivalent to the Evita 4, the Evita and the Servo 300 ventilators.
The Evita 2 dura integrates the optional functions for CO_2 and SpO_2 that are presently performed by the Evita 4.

Frank Clanzett
Regulatory Affairs Specialist

Mr. Harald Kneuer
Drager, Inc.
Critical Care Systems
4101 Pleasant Valley Road, Suite 100
Chantilly, Virginia   20151

AUG 26 1997

Re: K970165
      Evita 2 Dura
      Regulatory Class: II (two)
      Product Code: 73 CBK
      Dated: May 27, 1997
      Received: May 28, 1997

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 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/dsmamain.html".

Sincerely yours,
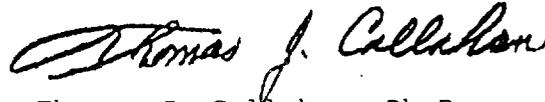
Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
   Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
   Radiological Health

Enclosure

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Intended use of the product

Evita 2 dura is a long-term ventilator for the intensive care ventilation of patients with a body weight of at least 3 kg up to 200 Kg.

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

- **CMV**   Intermittent Positive Pressure Ventilation
                   Controlled and assisted volume-constant ventilation

- **SIMV**   Synchronized Intermittent Mandatory Ventilation
                   Procedure for weaning patients off the ventilator after they have
                   started spontaneous breathing

- **MMV**   Mandatory Minute Volume Ventilation
                   Spontaneous breathing with automatic adjustment of mandatory
                   ventilation to the patient's minute volume requirement.

- **CPAP**   Continuous Positive Airway Pressure
                   Spontaneous breathing with positive airway pressure and adjustable
                   pressure support.

- **PCV+**   Presure Controlled Ventilation
                   Pressure-controlled ventilation combined with free spontaneous
                   breathing during the complete breathing cycle, and adjustable
                   pressure support from CPAP level.

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

Furthermore Evita 2 dura offers the following special ventilation modes :

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

- **ILV**   Independent Lung Ventilation, optional
                   Separate, differentiated, synchronised ventilation with one Evita 3
                   unit for each lung.

Application range

- Intensive care units

- Inner-clinical transport

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number _____ K970165

Prescription Use   _ OTC

Beier
(Project Manager)