K974176

Dräger

JUN | 7 1998

Datei: Sumstate.RTF
Date: 10/08/1997
Author: Frank Clanzett

510(k) SUMMARY
Summary of Safety and Effectiveness

APPLICANTS NAME AND ADDRESS:
Dräger Inc.
Critical Care Systems
~~4101-100 Pleasant Valley Road~~ 3136 Quarry Road
~~Chantilly, VA 20151~~ Telford, PA 18969

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:
Oct. 8, 1997

DEVICE NAME:

Trade Name:	Babylog 8000 plus
Classification Name:	Intensive Care Ventilator (per 21 CFR 868.5895)

LEGALLY MARKETED DEVICE TO WHICH DRÄGER IS CLAIMING SUBSTANTIAL EQUIVALENCE:

Babylog 8000 - Manufactured by Dräger Medizintechnik GmbH, Lübeck, Germany and sold in the United States by Dräger Inc.

Servo 300 - Sold in the United States by Siemens

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Brief description of the Babylog 8000 plus

The Babylog 8000 plus is an enhanced version of its predecessor Babylog 8000. It is a long-term, microprocessor-controlled, intensive care ventilator for premature and newborn babies, as well as for infants weighing up to about 10 kg.

The Babylog 8000 plus ventilates according to the continuous-flow principle with either time control or volume control, depending on the ventilation mode, and pressure limitation. Oxygen is metered out by the integrated air/O2 mixer.

A variety of the device functions are monitored in operation to make sure that safety-relevant failures are detected and safety for the patient is maintained.

The analog and digital interface is optionally available for connecting the Babylog 8000 plus to a device like a patient monitor or computer so that measured values and settings can be transferred to such equipment.

The ventilator can also be combined with a medicament nebulizer.

Indented Use of the Babylog 8000

The Babylog 8000 plus is a long term ventilator to be used in intensive care of premature and newborn babies and of infants up to 10 kg (22lbs).

The device provides the following ventilation modes:

CMV **C**ontinuous **M**andatory **V**entilation

A/C **A**ssist **C**ontrol Ventilation

SIMV **S**ynchronized **I**ntermittent **M**andatory **V**entilation

PSV **P**ressure **S**upport **V**entilation (available option)

CPAP **C**ontinuous **P**ositive **A**irway **P**ressure

Ventilation mode extension:

VG **V**olume **G**uarantee (available option), Volume controlled ventilation

VIVE **V**ariable **I**nspiratory, **V**ariable **E**xpiratory Flow

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Basis for the S&E - Decision

Characteristics	Servo 300	Babylog 8000	Babylog 8000 plus
510(k) number	K902859	K926292	under review
Manufacturer	Siemens	Dräger	Dräger
Classification	Intensive Care Ventilator	Intensive Care Ventilator	Intensive Care Ventilator
Control Principle	pressure-controlled or volume-controlled, time-cycled or flow-cycled; pressure-limited	time-controlled, time-cycled, pressure-limited	time-controlled or volume-controlled; time-cycled or flow-cycled; pressure-limited
Software controlled	yes	yes	yes
Ventilation modes:			
• CPAP	yes	yes	yes
• CMV	yes	yes	yes
• Assist Control	yes	yes	yes
• SIMV	yes	yes	yes
• PSV	yes	no	substantially equivalent to Servo 300
• VSV	yes	no	substantially equivalent to Servo 300
• PRVC	yes	no	substantially equivalent to Servo 300
• Manual inspiration	no	yes	like Babylog 8000
Method of triggering	Flow or pressure	Volume	like Babylog 8000
Ventilator settings:			
• Tin	10 to 80% of breath cycle time	0.1 to 2 s	like Babylog 8000
• Tex	via rate and Tin%	0.2 to 30 s	like Babylog 8000
• CMV rate	5 to 150 bpm	2 to 150 bpm (indirectly set via Tin and Tex)	like Babylog 8000
• SIMV rate	0.5 to 40 bpm	2 to 150 bpm (indirectly set via Tin and Tex)	like Babylog 8000

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Characteristics	Servo 300	Babylog 8000	Babylog 8000 plus
• I:E ratio	via rate and Tin%	1:300 to 3:1 (indirectly set via Tin and Tex)	like Babylog 8000
• O2 concentration	21 to 100 Vol%±3 Vol%	21 to 100 Vol%±3 Vol%	like Babylog 8000
• Pinsp	10 to 120 cmH2O	10 to 80 cmH2O	5 to 80 cmH2O
• PEEP	0 to 50 cmH2O	0 to 25 cmH2O	like Babylog 8000
• Insp. Flow	no	1 to 30 L/min continuous flow	like Babylog 8000
• Tidal Volume	adult: 2 to 4000 mL pediatric: 0 to 400 mL neonate: 0 to 40 mL	no	2 to 100 mL (when VG option is activated)
• Minute Volume	0.2 to 60 L/min	cannot be set; due to the control principle minute volume is result of ventilator settings and the characteristics of the respiratory system	like Babylog 8000
• Trigger sensitivity	0 to -17 cmH2O, or 0.7 to 2 L/min (adult); 0.3 to 1 L/min (pediatric); 0.17 to 0.5 L/min (neonate); (effective in all ventilation modes)	1 to 10 (=0 to 3 mL)	like Babylog 8000
• Trigger response time	not specified	40 to 60 ms at max sensitivity	like Babylog 8000
• Rise time	0 to 10% of breath cycle time	no	like Babylog 8000
Front panel controls	rotary dials and push buttons	rotary dials and push buttons; screen menu	like Babylog 8000
Display technology	LED indicators; LED array for pressure bargraph	LCD or ELD graphics screen; LED indicators; LED array for pressure bargraph	like Babylog 8000
Audible alarm	yes	yes	yes
Alarm sound level	adjustable	adjustable	like Babylog 8000
Pressure relief valve	120 cmH2O	120 cmH2O	like Babylog 8000

Characteristics	Servo 300	Babylog 8000	Babylog 8000 plus
Alarms:			
• Airway pressure high/low	yes	yes	yes
• O2 concentration low/high	yes	yes	yes
• Expired minute volume low/high	yes	yes	yes
• Apnea	yes	yes	yes
• Gas supply low/high	yes	yes	yes
• Breathing frequency low/high	no	no	yes (upper alarm limit only)
• Power failure	yes	yes	yes
• Battery supply voltage low/high	yes	NA	like Babylog 8000
• O2 cell disconnect	yes	yes	yes
• flow sensor error	yes	yes	yes
• pressure transducer error	yes	yes	yes
• Ventilator inop (technical alarms)	yes	yes	yes
Monitoring Parameters			
• peak airway pressure	yes	yes	yes
• mean airway pressure	yes	yes	yes
• PEEP	yes	yes	yes
• inspired tidal volume	yes	no	yes (not displayed)
• expired tidal volume	yes	yes	yes
• expired minute volume	yes	yes	yes
spontaneous fraction of expired minute volume	no	yes	yes
• percent leakage	no	yes	yes

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Characteristics	Servo 300	Babylog 8000	Babylog 8000 plus
• breathing frequency	yes	yes	yes
• rate-volume-ratio	no	no	yes
• compliance	no	no	yes
• resistance	no	no	yes
• FiO2	yes	yes	yes
• supply pressures	yes	yes	yes
Physical Characteristics:			
• dimensions WxDxH	242x370x240 mm (patient unit) 431x150x325 mm (control unit)	212x280x390 mm	like Babylog 8000
• weight	24 kg	14.5 kg	like Babylog 8000
Gas Supply			
• Supply gas pressure, O2 and air	29 to 94 PSI	45 to 90 PSI	like Babylog 8000
• Gas delivery system	microprocessor-controlled valves	microprocessor-controlled valve array (2x10 valves)	like Babylog 8000
Power supply			
• Mains voltage range	100, 120, 220 and 240 V, 50-60 Hz	85 to 140 V; 47 to 63 Hz	like Babylog 8000
• Power consumption	50 W	140 W	like Babylog 8000
• internal battery	yes	no	like Babylog 8000
• Operating time with internal battery	30 min	NA	like Babylog 8000
Special functions			
• Communications interface	serial port RS232 + analog output; Master/Slave connection	serial port RS232 + analog outputs (optional)	like Babylog 8000
• Medicament nebulizer	yes	yes	yes

Device performances compaired by Dr. Klaus Freudenstein / project manager

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Explanations of the Comparison

The ventilation modes of the Babylog 8000 plus that are not included in Babylog 8000 with the software 3.0 are substantial equivalent to ventilation modes of the Servo 300 ventilator of Siemens.

The additional monitoring features for the lung mechanics measurement like compliance, resistance and rate volume ratio may assist the user and are not essential for the safety and effectiveness concerning the intended use of the Babylog 8000 plus.

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

Dräger`s Babylog 8000 plus is substantial equivalent to either the Dräger Babylog 8000 or to the Siemens Servo 300 ventilator.

The Babylog 8000 plus functions are also covered by the predicate devices and the intended use of the Babylog 8000 plus is covered by the predicate devices, too.

The Babylog 8000 plus fulfills at least the same technical standards as the predicate device of Dräger and has been tested according to these standards.

Therefore the device is as safe and effective as the predicate devices.

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Oct. 8, 1997

Frank Clanzett
Quality Management,
Regulatory Affairs
Dräger Medizintechnik GmbH, Lübeck, Germany

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 1998

Mr. Harald Kneuer
Dräger, Inc.
Critical Care System
3136 Quarry Road
Telford, PA 18969

Re: K974176
BABYLOG 8000 Plus
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: March 1, 1998
Received: March 19, 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 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

Indented Use Statement for the Babylog 8000

The Babylog 8000 plus is a long term ventilator to be used in intensive care of premature and newborn babies and of infants up to 10 kg (22 lbs).

The device provides the following ventilation modes:

CMV Continuous **M**andatory **V**entilation

Time-controlled, time-cycled, pressure-limited continuous flow ventilation.

A/C **A**ssist **C**ontrol Ventilation

Time-controlled, volume triggered, time-cycled, pressure-limited continuous flow ventilation that is synchronized with each spontaneous patient breath.

SIMV **S**ynchronized **I**ntermittent **M**andatory **V**entilation

Time-controlled , volume triggered, flow cycled, pressure-limited continuous flow ventilation, synchronized with patient's spontaneous breathing at the set ventilation rate.

PSV **P**ressure **S**upport **V**entilation (available option)

Time-controlled , volume triggered, flow cycled, pressure-limited ventilation synchronized with each spontaneous patient breath.

CAP Continuous **P**ositive **A**irway Pressure

Spontaneous breathing with positive airway pressure

Ventilation mode extension:

VG **V**olume **G**uarantee (available option), Volume controlled ventilation.

The ventilator controls inspiratory pressure in order to deliver the preset tidal volume. May be combined with A/C, SIMV and PSV.

VIVE **V**ariable **I**nspiratory, **V**ariable **E**xpiratory Flow

Separate continuous flow during expiration in mandatory ventilation modes.

Klaus Freudenstein

Dr. Klaus Freudenstein
(project manager)

M. Ryan

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K974176

☑ FOR PRESCRIPTION USE