K971198

OCT - 3 1997

Dräger

Datei: Summary.RTF
Date:Jan.08, 1997
Author: Frank Clanzett

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

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:
January 08, 1997

DEVICE NAME:

Trade Name:	Babytherm 8004 / 8010
Common Name:	Babytherm 8004 / 8010
Classification Name:	System, Thermal Regulating

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

Babytherm 8000 WB - Manufactured by Dragerwerk AG, Lubeck, Germany and sold in the United States by Drager Inc.

RH 600 (Radiant Heater) - Manufactured by Dragerwerk AG, Lubeck, Germany and sold in the United States by Drager Inc.

PT 4000 (Phototherapy) - Manufactured by Dragerwerk AG, Lubeck, Germany and sold in the United States by Drager Inc.

Microlite™ (Phototherapy) - Manufactured by Air Shields, USA

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Table of Comparison

	Dräger Babytherm 8000 WB	Dräger Radiant Heater RH 600	Dräger PT4000	AirShields Microlite™	*Dräger Babytherm 8004 / 8010*
510(k) Number	K 94 5467	K 95 3489	K 95 4611	K 91 2908	
Intended Use	Heated bassinet intended as a therapeutic device providing warmth for premature and full-term neonates and infants with a weight up to 16 lbs.	Radiant warmer system to compensate for heat lost by infants during medical examinations or therapy.	PT 4000 is used to decrease blood bilirubin levels via phototherapy in premature and full term infants who are treated in incubators or on radiant warmer beds.	Phototherapy for treatment of Hyp erbilirubinemia	Babytherm 8004 / 8010 is an infant warmer system intended as a therapeutic device providing warmth for premature and full-term neonates and infants with a weight up to 16 lbs. It is intended for use in delivery rooms, neonatal wards, neonatal and paediatric intensive care units. Both Systems can be equipped with the optional phototherapy system for treatment of Hyperbilirubinemia.
Physical Size (mm)					
Height (mm)	1220 to 1515 with height adjustment	-----	-----	-----	1820 to 2385 with height adjustment
Length (mm)	1070	-----	-----	-----	1315
Width (mm)	750	-----	-----	-----	like Babytherm 8000 WB
Weight	85 kg max	-----	-----	-----	135 kg max
Mattress Size (mm)	750 x 490	-----	-----	-----	like Babytherm 8000 WB
Bassinet Tilt	± 10° from horizontal	-----	-----	-----	like Babytherm 8000 WB
Case Material	PS-TSG	-----	-----	-----	like Babytherm 8000 WB
Case Color	blue	-----	-----	-----	like Babytherm 8000 WB
Power Input					
Voltage	120 VAC, 60 Hz	110 / 127 VAC, 60 Hz	110 / 127V	110 / 120 VAC	like Babytherm 8000 WB
Total	135 W + 560 W for height adjustment	735 W	120 W	300 W	670 W for Babytherm 8004 790 W for Babytherm 8010 +120 W for variable height adjust + 440 W for Phototherapy
Fuses	2 x 1.6 A / 2 x 6,3 A	2 x 6.3 A	2 x 1.6 A	2 x 4 A	2 x 15 A
Leakage Current	< 0.2 mA	< 0.1 mA	< 0.2 mA	< 0.1 mA	< 0.5 mA

[1] see explanation of differences

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	Dräger Babytherm 8000 WB	Dräger Radiant Heater RH 600	Dräger PT4000	AirShields Microlite™	*Dräger Babytherm 8004 / 8010*
Design	Heated Mattress Control and heater unit and the mattress are together in one housing which is mounted on a trolley with optional height adjustment and four casters	Radiant Warmer Control and heater unit are together in one housing which is mounted on mobile stand or on a wall.	Phototherapy The Photo-therapy is a separate device with an examination light included.	Phototherapy The Photo-therapy is a separate device	The Babytherm 8004 / 8010 is developed to combine the two products Dräger Babytherm 8000 WB and Dräger Radiant warmer RH600. Components of the Heated Mattress (Babytherm 8010 only) are the same as for Babytherm 8000 WB. The ThermoMonitoring is included in the Babytherm 8004 and 8010. [1] The Radiant Warmer of the Babytherm 8004/8010 is a further development of the RH 600.The Heater unit, the examination light and the optional Phototherapy unit are together in one housing which is located in a distance of 80 cm over the matress, mounted on two columns at the head end of the bed. The Control Unit is located below the end of the radiant warmer between the two columns at the head end of the bed.
Energy used	Electric: A 120 W, 24 VAC heater heats up an aluminium plate and the patient is heated up by conductive warm through the Gel mattress. The lower heater voltage of 24 VAC insures maximum safety for the patient.	Electric: Four 150 W, 120 VAC ceramic heater are used to provide radiative heat in direction of the bed.	Electric: Flourescent bulbs for the phototherapy	Electric: Halogen bulbs for the phototherapy	Electric. For the heated mattress the same as Babytherm 8000 WB. For the radiant warmer two ceramic heater of 300 W are used to provide radiative heat in the direction to the bed. [2] For the phototherapy halogen bulbs are used
Heated Mattress					
Type	4 mm Aluminium plate with heating foil	------	-----	-----	like Babytherm 8000 WB
Power	24 VAC / 120 W	------	------	-----	like Babytherm 8000 WB

[1] see explanation of differences

	Dräger Babytherm 8000 WB	Dräger Radiant Heater RH 600	Dräger PT4000	AirShields Microlite™	*Dräger Babytherm 8004 / 8010*
Heated Mattress (Continue)					
Setting Temp. Range	30.0°C - 38.0°C	------	-----	-----	like Babytherm 8000 WB
Measurement Range	5.0°C - 45.0°C	------	-----	-----	like Babytherm 8000 WB
Accuracy	± 0.5 °C	------	-----	-----	like Babytherm 8000 WB
Applied Part	BF	------	-----	-----	like Babytherm 8000 WB
Radiant Heater					
Type	------	ceramic	-----	-----	like RH 600
Power	------	600 W	-----	-----	like RH 600
Control	------	manual or servo	-----	-----	like RH 600
Distance heater - mattress	------	70 cm default, possible 60cm to 80 cm	-----	-----	80 cm
Exam light	------	1 x 35 W	-----	-----	1 x 11 W, 1 x 19 W
Manual setting	------	Level 0 to 10, 23 mW/cm² max. at 70 cm distance	-----	-----	Level 0 to 10, 30 mW/cm² max. at 80 cm [3]
Setting Temp. Range	------	35°C - 37°C	-----	-----	35°C - 37.5 °C [4]
Measurement Range	------	33°C - 38°C	-----	-----	15°C to 42 °C [5]
Accuracy	------	± 0.3 °C	-----	-----	like RH 600
Applied Part	------	B	-----	-----	BF [6]
Power Fail	Actuates if there is a loss of supply voltage	Actuates if there is a loss of supply voltage	-----	-----	Actuates if there is a loss of supply voltage

[n] see explanation of differences

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	Dräger Babytherm 8000 WB	Dräger Radiant Heater RH 600	Dräger PT4000	AirShields Microlite™	*Dräger Babytherm 8004 / 8010*
Phototherapy Option					
Type	-----	-----	Phototherapy system mounted on a mobile stand for use in combination with radiant warmers or incubators	Phototherapy system mounted on a mobile stand for use in combination with radiant warmers or incubators	Phototherapy system integrated in radiant warmer housing for use in combination with radiant warmer, mounted on two columns at the head end of the bed, with a fixed distance to the patient
Light source	-----	-----	flourescent bulbs	3 halogen bulbs	6 halogen bulbs [7]
Power input	-----	-----	120 W	300 W	440 W [8]
Distance to mattress	-----	-----	variable, 30 cm minimum	variable	80 cm
On/Off switch	-----	-----	yes	yes	yes
effective Irradiance within Wave length range	-----	-----	13 µW/cm²/nm at 40 cm distance 400..500 nm	17 µW/cm²/nm at 43 cm distance 400..500 nm	12 µW/cm²/nm at 80 cm distance 425..475 nm
Bulb life	-----	-----	1000 hours	1000 hours	1000 hours
Hour meter	-----	-----	dual timing system for patient exposure time and bulb life	dual timing system for patient exposure time and bulb life	dual timing system for patient exposure time and bulb life.
Control System					
Type	Microprocessor based, digital	Microprocessor based, digital	-----	-----	Microprocessor based, digital
Self-Calibrating	Yes	Yes	-----	-----	Yes
Setpoint-Readout	Digital, 3 digit	Digital, 3 digit	-----	-----	Digital, 3 digit
Power On	Red LED	Red LED	-----	-----	Green LED [9]
Power Fail	Actuates if there is a loss of supply voltage	Actuates if there is a loss of supply voltage	-----	-----	Actuates if there is a loss of supply voltage

[n] see explanation of differences

	Dräger Babytherm 8000 WB	Dräger Radiant Heater RH 600	Dräger PT4000	AirShields Microlite™	*Dräger Babytherm 8004 / 8010*
Safety System					
Overtemperature	40.0°C	-------	-----	-----	For mattress: like Babytherm 8000 WB. For skin temp. 39.0°C in skin mode or in manual mode, if sensor is connected. [10]
Overheat Protection	Yes.	Yes.	-----	-----	Yes
Probe Fail	Actuates if mattress temp. sensors (2 pairs) are open, shorted or un-plugged, or if temp. difference between mattress sensors is too large	Actuates during skin temp. control if skin temp. probe has been disconnected or is faulty	-----	-----	For mattress: Like Babytherm 8000 WB. For radiant heater: like RH 600
Set point deviation	Mattress Set temp. ± 1°C	Skin Set temp. ± 0.5°C	-----	-----	For mattress, same as Babytherm 8000 WB. For skin temp., like RH 600 [11]
Shut off temperature	42.0°C	-----	-----	-----	like Babytherm 8000 WB.
15 Minute Alarm	------	Actuates after 15 minutes in manual mode with level > 5	-----	-----	Actuates after 15 minutes in manual mode with level > 3, and heater output is reduced to level 2 [12]
Visuable Alarm	Yes	Yes	-----	-----	Yes.
Audible Alarm	Yes	Yes	-----	-----	Yes.

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Explanation of Differences related to the Table of Comparison:

1 The ThermoMonitoring function uses two sensors for temperature measurement: One for the peripherally and one for the core sensor.
2 For the Babytherm 8004 / 8010 other types of ceramic heaters are used. The geometry of the reflectors was improved. The performance still meets the requirements of IEC 601-2-21.
3 The maximum irradiance was improved because of better reflector geometry. The device still meets the requirements of IEC 601-2-21.
4 This is an improved performance. The device still meets the requirements of IEC 601-2-21.
5 Two temperature channels for core and peripheral temperature with a range from 15°C to 42°C.
6 This is an improved safety requirement of IEC 601-2-21.
7 By this modification an even distribution of the irradiance over an area of 20 x 40 cm is achieved.
8 see explanation number 7.
9 Change in LED Colour to fullfill exactely this requirement of IEC 601.
10 This is an improved safety feature for the radiant heater.
11 The allowable deviation may be changed by the user in a range from 0.3°C to 1.0°C
12 For the Babytherm 8004/8010 at level 3 the heater output is approximately 9 mW/cm², level 2 corresponds to heater output of 6 mW/cm². According to 601-2-21 the 15 Minutes-Alarm has to be activated at a heater output of more than 10 mW/cm².

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DESCRIPTION OF THE DEVICE:

Babytherm 8004 / 8010 is a warmer system for infants that provides a combination of a heated mattress (Babytherm 8010, only), a radiant heater and an optional phototherapy system. The radiant heater is in a fixed position over the mattress and is equipped with an examination light. The phototherapy system can be installed by the manufacturer or by the biomedical engineer in the housing of the radiant heater.

Babytherm 8004 provides warmth by a radiant heater in "manual mode" or with "skin temperature control".
Babytherm 8010 provides warmth by a radiant heater in "manual mode" or with "skin temperature control". The Babytherm 8010 also has a heated gel mattress for conductive warmth.

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

The Babytherm 8004 / 8010 are substantially equivalent to the predicate devices Babytherm 8000 WB, Radiant Heater RH 600, Phototherapy PT 4000 and Phototherapy Microlite™.

The function of the Babytherm 8004 / 8010 including the optional Phototherapy is also covered by the predicate devices and the equivalent intended use is covered by these devices, too.

The Babytherm 8004 / 8010 fulfil at least the same international standards as the predicate devices of Dräger and has been tested according to these standards. Therefore the Babytherm 8004 / 8010 are as safe and effective as the predicate devices.

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Frank Clanzett
Regulatory Affairs Specialist
(Dragerwerk AG, Germany)

Jan. 08.1997

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT - 3 1997

Mr. Harald Kneuer
Regulatory Affairs Manager
Drager Incorporated
4101 Pleasant Valley Road, Suite 100
Chantilly, VA 20151

Re: K971198
Trade Name: Babytherm 8004 Babytherm 8010
Regulatory Class: II
Product Code: FMT
Dated: July 7, 1997
Received: July 9, 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 requirement, 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) 594-4618. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INTENDED USE OF THE DEVICE:

Babytherm 8004 / 8010 is an infant warmer system intended as a therapeutic device providing warmth for premature and full-term neonates and infants with a weight up to 16 lbs. It is intended for use in delivery rooms, operating theatres, maternity and obstetric units, neonatal wards, neonatal and paediatric intensive care units.
Both Systems can be equipped with the optional phototherapy system for treatment of Hyperbilirubinemia.

Frank Clanzett
Regulatory Affairs Specialist
(Dragerwerk AG, Germany)

Jan. 08.1997

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971198

Prescription Use ✓
(Per 21 CFR 801.109)

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