

MAY 29 1998

K980886

Summary of Safety and Effectiveness Data Relating to Substantial Equivalence

Proprietary Name: Babytherm 8000 LDR

Classification Name: Water Circulating Hot or Cold Pack 89ILO

Device Class: Class II

Manufacturer: North American Dräger
3135 Quarry Road
Telford, Pennsylvania 18969

Establishment Registration Number: 2517967

Devices to which substantial equivalence is claimed: Babytherm 8000 WB K94567

Device Description:

The Babytherm 8000 LDR is an infant warming bed which provides therapeutic warmth for premature and full-term neonates, and infants.

Intended Use:

The Babytherm 8000 LDR is intended for use as a warming bed in labor and delivery suites, neonatal wards, neonatal intensive care units, and for short transports inside the hospital

Substantial Equivalence:

The Babytherm 8000 LDR is substantially equivalent to the Babytherm 8000 WB.

The Babytherm 8000 LDR and the Babytherm 8000 WB have the same intended use and principal of operation and are substantially equivalent.

Qualification of the Babytherm 8000 LDR included a hazard analysis, system level qualification testing, and environmental testing.



MAY 29 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James J. Brennan
Director Regulatory Affairs
North American Drager
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K980886
Trade Name: Babytherm 8000 LDR
Regulatory Class: II
Product Code: FMZ
Dated: March 6, 1998
Received: March 9, 1998

Dear Mr. Brennan:

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.

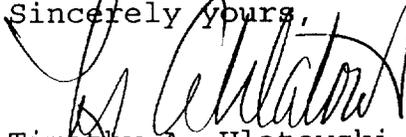
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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

510(k) Number (if known): _____

Device Name: Babytherm 8000 LDR

Indications for Use:

The Babytherm 8000 LDR is indicated as a therapeutic device for providing warmth with or without the use of a canopy for premature and full-term neonates and infants up to 16 lbs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Patricia Cuente
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980886

(Optional Format 1-2-96)