

Ohmeda Medical OmniBed

510(k) Summary

Submitter Information

Alberto F. Profumo, RAC
9065 Guilford Road
Columbia, MD 21046-1801
Tel. (410) 381- 4004
Summary prepared on September 30, 1999

Device Name(s)

Classification Names:

- Neonatal Incubator
- Infant Radiant Warmer

Common Names:

- Incubator
- Infant Radiant Warmer

Proprietary Name:

- Ohmeda Medical - OmniBed

Predicate Device Information

The OmniBed is substantially equivalent to the following, legally marketed products:

- Ohmeda - Ohio Care Plus Incubator (all models)
- Ohmeda - Ohio Infant Warmer System (all models)
- Ohmeda – Ohio Intensive Care Incubator

Indications for Use

The OmniBed is a combination of an infant incubator (“incubator”) and an infant radiant warmer (“warmer”)

Incubators and warmers provide heat in a controlled manner to neonates who are unable to thermoregulate based on their own physiology. Incubators provide an enclosed, temperature controlled environment and warmers provide infrared heat in an open environment. They may also be used for short periods of time to facilitate the neonate’s transition from the uterus to the external environment. Most incubators and warmers can be used in two operating modes:

1. Air Control: The clinician sets the appropriate air temperature (in an incubator) or the appropriate heat output (in a warmer) for maintaining the desired patient temperature. These parameters are initially selected based on the clinician’s training and experience, and then are adjusted based on the patients’ needs and clinical status.

2. Patient Control: The clinician sets the desired patient temperature. A skin temperature probe senses the patient temperature and feeds this information to the controller of the incubator. The controller then adjusts the heater output to maintain the patient temperature at the set value. These adjustments to the heater output are made in such a way to gradually change the patient's temperature while minimizing overshooting and patient stress.

Incubators and warmers have alarms to alert clinicians when certain patient or equipment conditions occur, such as a malfunction, or an excessive departure of the patient's temperature from the set value.

Incubators and warmers may incorporate other features such as tilting of the bed, oxygen supply, and data output to remote monitors or nurse call systems. Incubators may provide humidification of the enclosed infant environment.

The device can be operated as conventional incubator or as a conventional infant radiant warmer, but both modes of operation cannot be active at the same time.

Product Description

The Ohmeda Medical OmniBed is an infant bed which provides thermal support for infants who are unable to provide for their own heat requirements. This bed has two modes of operation, enclosed bed operation and open bed operation.

In the enclosed bed mode of operation, the bed functions as an incubator, maintaining the infant's temperature by circulating heated air within the enclosed bed compartment. The operator may select either the air or skin temperature control method. Depending on the control method selected, heat is regulated based on either the air temperature or the infant's skin temperature compared to the operator selected control temperature. Physical access to the patient is obtained through the side portholes or by opening one of the side doors. In the enclosed bed mode, humidity and oxygen may also be increased.

In the open bed mode, this bed operates like a convention open, radiantly heated infant bed. Radiant heat from an infrared heat source is focused on to the bed to warm the patient. The operator may select either the heater power or skin temperature control method. Depending on the control method selected, the heater is either regulated at the operator selected power level or the heater output is modulated to maintain the patient's temperature at the value selected by the operator.

This bed can be changed from either mode to the other by the activation of a foot or hand operated switch. The hood canopy will automatically open or close creating either an open or enclosed bed respectively. It should be noted that the device can be operated as conventional incubator or as a conventional infant radiant warmer, but both modes of operation cannot be active at the same time.

Assessment of Technological Characteristics

The technological characteristics of the OmniBed are similar to those of the predicate devices and do not raise new safety or effectiveness issues.

Performance Data

Since care of newborns in incubators and warmers is a well established clinical practice, Ohmeda submits that clinical or animal testing to demonstrate safety and effectiveness is not necessary. The product was subject to extensive bench testing, the software was validated, and, to the best of Ohmeda Medical's knowledge, the requirements of 21 CFR 820, Subpart C -- Design Controls -- were satisfied.

Sterilization Information

The OmniBed is not intended to be sterilized. Cleaning and disinfection instructions can be found in the Operations and Maintenance Manual.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Alberto F. Profumo, R.A.C.
Director, Product Assurance
Ohmeda Medical
9065 Guilford Road
Columbia, MD 21046-1801

Re: K993407
Trade Name: Ohmeda Medical OmniBed
Class: II
Product Code: FMZ
Dated: September 30, 1999
Received: October 8, 1999

Dear Mr. Profumo:

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.

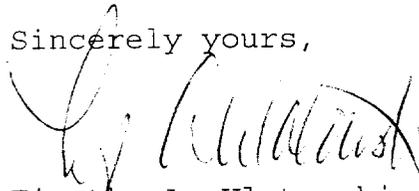
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR

Over-The Counter Use (Optional Format 1-2-96)

Valencia Cicchetti
(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number 1993407