Ohmeda - Ohio® Care Plus® Incubator (modified)
510(k) Summary

K974349
Feb. 12, 1998

1. Predicate Device Information

The modified Care Plus Incubator is substantially equivalent to the currently marketed Care Plus Incubator.

2. Intended Use Statement

Incubators provide a controlled thermal environment for neonates who are unable to provide their own thermoregulation. 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 can be used in two operating modes:

1. Air Control: The clinician sets the appropriate air temperature for maintaining the desired patient temperature. The air temperature is initially selected based on the clinician's training and experience and then is 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 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 may incorporate other features, such as humidification of the infant environment, tilting of the bed, oxygen supply, and data output to remote monitors or nurse call systems.

3. Description of the Modifications

The modifications which are the subject of this submission are summarized below:

a) Created two new models --Care Plus 1000/2000 modified as follows:

   i) The front control switch panel has been simplified to contain non-language specific symbols with a legend located above the front panel which explain the meaning of these symbols.
   ii) Twenty-three labels affixed to the current Care Plus have been consolidated into five labels.
   iii) The tilt mechanism has been simplified to provide two (0° and 10°) rather than three (0°, 3°, and 6°) tilt positions. Continuous tilt is not an available option for these models

iv) The hood assembly (including the portholes, front access door, and inner walls) have been partially modified to improve access to the infant and reduce cost.

v) The refresher instructions located on the unit have been eliminated (a complete set of instructions continues to be provided in the Operation and Maintenance Manual). the refresher instructions continue to be provided with the Care Plus 3000 and 4000.

vi) The passive humidifier, standard in the Care Plus 3000, has been made an optional feature in these models. The servo-controlled humidifier, standard in the Care Plus 4000 is not an available option for these models

vii) The material of the optional humidifier tray has been changed from Polysulfone to polypropylene.

viii) The Care Plus 1000 can be operated in one mode (air control) only rather than in the two modes (air control and patient control) available in the other models.

b) Modified the printed circuit boards included in all models (1000, 2000, 3000, and 4000) to incorporate surface mount technology rather than the current through hole technology.

c) An optional, larger hood is available for Care Plus 3000 and 4000.

4. Assessment of Technological Characteristics

The only change in the technological characteristics of the device is the use of Surface Mount Technology (SMT) printed circuit boards instead of through hole printed circuit boards. Ohmeda submits that this change does not raise new issues of safety or effectiveness because SMT is a very mature technology, widely used in most computer and other electronic equipment manufactured today. In fact, the currently used technology (through hole printed circuit boards) is rapidly becoming obsolete and the availability of components for this technology is decreasing as time goes by.

5. Performance Data

Since (1) care of newborns in incubators is a well established clinical practice and (2) the modifications which are the subject of this submission do not change the way in which treatment is being administered, Ohmeda submits that clinical or animal testing to demonstrate safety and effectiveness is not necessary. The design changes were verified by bench testing and the labeling change was user validated.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

FEB 12 1998

Re: K974349
Trade Name: Ohmeda-Ohio Care Plus Incubator
Regulatory Class: II
Product Code: FMZ
Dated: November 10, 1997
Received: November 19, 1997

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 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

2

510(k) Number (if known):

Device Name: Ohio® Care Plus® Incubator

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Patricia Cruente
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974349

Prescription Use ✓ OR Over- The Counter Use ____
(Per 21 CFR 801.109)