K962806

SEP 20 1996

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

1. Predicate Device Information

The modified Care Plus Incubator which is the subject of this Premarket Notification is substantially equivalent to the currently marketed Care Plus Incubator. A description of the modification that made this submission necessary is provided in the Functional Description section of this summary.

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.

2. Functional Description

All functions of the modified Care Plus Incubator, with the exemption of the optional communications module, remain the same as in the predicate device. The current Care Plus Incubator includes an optional RS-232 communications module (ThermaLink) that interfaces with the SpaceLabs Flexport monitors or other monitors that adhere to the ThermaLink protocol. The communications module of the modified Care Plus Incubator will also be able to interface with the Hewlett Packard VueLink monitor using the Hewlett Packard proprietary protocol. This change does not affect the operation (displays, alarms, user's controls, etc.) of the incubator. The hardware and software of the incubator controller have not been changed. A microcontroller has been added to the communications module printed circuit board to (a) identify the connected monitor and (b) output data to the monitor using the applicable protocol.

4. Assessment of Technological Characteristics

Technological characteristics of the modified Care Plus Incubator remain the same as in the predicate device. The existing Care Plus Incubator already incorporates microcontrollers to control temperature and humidity. The addition of a third microcontroller to output information to monitors using different protocols does not change the technological characteristics of the device

5. Performance Data

Since (1) care of newborns in incubators is a well established clinical practice and (2) the modification which is the subject of this submission does not affect the basic operation of the incubator , Ohmeda submits that clinical or animal testing to demonstrate safety and effectiveness is not necessary. The modified design will be verified by bench testing.