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Ohmeda - Ohio® Infant Warmer System
510(k) Summary

1. Device Information:

   a) Proprietary Name: Ohmeda - Ohio Infant Warmer System
   b) Common Name: Infant Radiant Warmer
   c) Classification Name: Infant Radiant Warmer
   d) Regulatory Class: III
   e) Classification Panel: General Hospital
   f) Classification Code: 80FMT
   g) Regulation: 21 CFR 880.5130

2. Manufacturers Information:

   Ohmeda, Inc.
   Specialty Products Division
   9065 Guilford Road
   Columbia, MD 21046-1801
   Contact Person: Alberto F. Profumo, Director of Product Assurance

3. Predicate Device Information

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

4. Intended Use Statement

   Infant radiant warmers provide infrared heat, in a controlled manner, to neonates who are unable to thermoregulate based on their own physiology or necessitate external heat to smoothen the transition from the uterus to the external environment. They fulfill the same purpose of neonatal incubators but they may be preferred over incubators when total access to the patient is needed or desirable (e.g., surgical procedures, extracorporeal membrane oxygenation, frequent resuscitation, etc.). Most infant radiant warmers can be used in two operating modes:

   a) Manual: The clinician sets the appropriate heater output for maintaining the desired patient temperature. The heater output is initially selected based on the clinician's training and experience and then is adjusted based on the patients' needs and clinical status.

   b) Servo: The clinician sets the desired patient temperature. A skin temperature probe senses the patient temperature and feeds this information to the controller of the infant radiant warmer. 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.

   Infant radiant 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.

   Infant radiant warmers may incorporate other features, such as phototherapy, observation light, tilting of the bed, and data output to remote monitors or nurse call systems.

5. Functional Description

All functions of the modified IWS, with the exemption of the optional communications module, remain the same as in the predicate device. The current IWS 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 IWS 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 IWS 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.

6. Assessment of Technological Characteristics

Technological characteristics of the modified IWS remain the same as in the predicate device. The existing IWS 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.

7. Performance Data

Since (1) care of newborns in infant radiant warmers 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.

Prepared by: Alberto F. Profumo Date: 8/5/96