HEALTHCARE

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K972885

OCT 30 1997

30 July, 1997

510(k) Summary of Safety and Effectiveness Information

Model No. / Name: **IW960 Servo-Control Wall-Mount CosyCot™ Infant Warmer**
IW970 Manual-Control Wall-Mount CosyCot™ Infant Warmer
Classification Name: Warmer, Infant Radiant - 80 FMT
General Hospital Devices, 21 CFR §880.5130 (Class III)
Predicate Devices: Ohmeda, Ohio Infant Warmer System, Model 3150, K921766
Fisher & Paykel, RD1000 Infant Resuscitator, K892885

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Fisher & Paykel Healthcare IW960 Servo-Control and IW970 Manual-Control Wall-Mount CosyCot Infant Warmers consist of a heater assembly, controller unit, support column, built-in bed assembly, and wall mounting hardware components.

The heater assembly includes a single rod infrared heating element housed inside a parabolic reflector. An observation lamp is mounted at the back of the heater unit. The thermoplastic enclosure is of similar cross-sectional shape to the reflector and is approx. 125mm high × 197mm wide × 625mm deep. It can be rotated to either side of the warmer, clear of the infant bed. A metal grill on the underside of the heater assembly prevents contact with the element.

The heater assembly is mounted on top of the support column, which consists of a single aluminum extrusion section with thermoplastic front panel sections attached. Instruction / warning labeling is located on the back at the top of the support column, with a duplicate copy of label instructions provided. Identification / specification labeling is located on the front panel at the base of the support column, with the power inlet and auxiliary power outlet sockets. The dimensions of the support column are approx. 1448mm high × 193mm wide × 90mm deep (104mm deep at controller section top). The column section is supported by dual wall-mounting brackets, attached to the top and bottom of the column extrusion.

The controller unit is built into the top of the support column. The transformer and Power PCB are mounted to the aluminum extrusion back section. The Control PCB is mounted on the inside of the thermoplastic front panel. This panel contains the control buttons, displays, main power switch and temperature sensor socket. Controls consist of buttons to select operating modes, timer functions and lamp operation. A control knob selects temperature or power level. LED displays include indicators for operating mode, alarms, timer, lamp and heater power, and 3-digit displays for temperature and timer readings.

The bassinet assembly is supported by a four-bar link system attached to the support column extrusion. It consists of a stretched fabric surface over an aluminum extrusion frame. Removable barriers on each side may be folded down for access to an infant, and latch into clips in the bassinet frame. The bassinet may be tilted continuously through +10° to -10° to achieve Trendelenburg and Fowler positions. A spring-loaded cable brake system is used to change the tilt position. An x-ray tray module can be mounted underneath the bassinet for placement of an x-ray cassette. The bassinet assembly is approx. 650mm square × 86mm high, with side barrier panels 127mm above the bassinet surface.

A variety of accessory mounting and storage options are available. Infant resuscitator and oxygen flowmeter modules may be mounted in column front panels. A gas supply module may be mounted to the back of the support column extrusion. The column extrusion features a channel mounting system in either side to support mounting blocks for further accessories, which may be fixed at the required height. These include short and long mounting poles, side shelves, gas supply and venturi suction unit mounting blocks and accessory hooks. Storage trays and bins may also be mounted under the bassinet area using this mounting system.

In Baby mode, the IW960 provides stable control of the baby's skin temperature by automatically adjusting the heater power to compensate for varying metabolic and environmental conditions. In Manual mode, both the IW960 and IW970 provide user-adjustable heater power. In Prewarm mode, the IW960 and IW970 maintain power at a constant level of 25% ready for use.
A double thermistor sensor probe measures the baby's skin temperature, and audible and visual alarms alert the user to high or low temperature situations, equipment fault, power failure and periodic reminders to reassess the baby's clinical condition, depending on the control mode being used. Various independent safety features are included to control maximum output and avoid thermal injury to the infant.

The intended use of Infant Radiant Warmers is to provide thermal support for newborn babies in the first few weeks of life. This may include in the delivery room in the period immediately after birth, and in the neonatal intensive care unit for critically ill babies which may require frequent intervention from hospital personnel.
New-born babies (including low birth-weight or premature infants) and critically ill babies may have a reduced self-thermoregulation capacity. Body heat can be lost through the mechanisms of conduction, convection, radiation and evaporation. Low quantities of internal energy and insulating fat, and a high surface area-to-mass ratio can also be contributing factors. In these cases, or when thermal support is required or desirable, radiant heat may be provided to prevent the various clinical consequences of excessive heat loss.

Infant Radiant Warmers contain an infrared heating element intended to be placed over an infant in a pediatric hospital bed, to maintain an infant's body temperature by means of controlled radiant heat. Heat energy is absorbed through an infant's skin, increasing local blood flow which transfers heat to the rest of the body by blood convection and tissue conduction.
Situations which necessitate unobstructed access to an infant, including during resuscitation or surgical procedures, may indicate the need for a radiant heat source instead of equivalent support devices such as infant incubators.
The object of providing controlled radiant heat is to stabilize the infant's temperature at the level where metabolic rate is at a minimum. At this state the infant's internal energy sources are used primarily for growth and healing, and not trying to keep warm or cool.

The technological characteristics of the IW960 and IW970 Wall-Mount CosyCot Infant Warmers are equivalent to those of the predicate device.
The built-in bed assembly and wall-mounting configurations, location of heater and controller sections, and capacity to swing aside the heater section are equivalent. Both feature a single-bar radiant heating element with a parabolic metal reflector design. Heater output is regulated by microprocessor-controlled circuitry. The modes of operation, alarm configurations and user controls are very similar between the devices. Both devices use self-monitoring software and hardware options to ensure device faults are detected and do not result in hazardous states. The power used and irradiance levels achieved on a mattress surface by the two devices are very similar in quantity.

Improvements in safety and effectiveness include the use of a dual-thermistor skin temperature sensor, the comparison of readings from which allows the equipment to detect any variation in the sensor performance, and ensure accurate temperature measurement. The temperature controlling system and software used to regulate this allow for very accurate and stable control of an infant's skin temperature, hence providing optimal environmental clinical conditions.

Performance testing for the IW960 and IW970 has been carried out in the areas of functional verification, temperature control, irradiance distribution patterns and clinical verifications.
This testing demonstrates the safety, uniform distribution, accuracy and absolute accuracy of temperatures achieved on an infant bed, and the qualitative nature of the irradiance distribution pattern on the mattress, including irradiance in specific regions of the infra-red spectrum. Clinical verification studies demonstrated the ability of the warmers to warm up babies to a stable desired set temperature level accurately in a short period of time, and the ability to control the set temperature very accurately for a stable situation. The proposed devices meet specific aspects of performance required by the standard for Infant Radiant Warmers, IEC 601-2-21, including:

- temperatures achieved on the mattress surface for different materials.
- temperature distribution and variance across the mattress surface.
- accuracy of temperature control in the servo-controlled mode.
- absolute accuracy of temperature measurement against an external comparison.
- maximum irradiance levels for overall IR and near IR spectrum regions.

The product testing carried out for the IW960 and IW970 Wall-Mount CosyCot Infant Warmers indicate that they meet their design and performance functional requirements. Clinical verification studies demonstrate the successful use of the warmers and their ability to provide accurate and stable warming of infants. The proposed devices also meet the requirements of the international standard for Infant Radiant Warmers, IEC 601-2-21.

signed: _____ date: 30 July 1997

Chris Mander
Fisher & Paykel Healthcare

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Mr. Chris Mander
Regulatory Affairs Engineer
Fisher & Paykel Electronics Ltd.
Healthcare Division
25 Carbine Road
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New Zealand

OCT 30 1997

Re: K972885
Trade Name: Servo-Control Wall-Mount Cosycot Infant Warmer Model IW960 and IW970
Regulatory Class: II
Product Code: FMT
Dated: July 30, 1997
Received: August 5, 1997

Dear Mr. Mander:

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

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Fisher & Paykel IW960 and IW970 Wall-Mount CosyCot Infant Warmers

PREMARKET NOTIFICATION 510(k)
INDICATIONS FOR USE STATEMENT

The Fisher & Paykel Healthcare IW960 Servo-Control Wall-Mount CosyCot Infant Warmer and IW970 Manual-Control Wall-Mount CosyCot Infant Warmer are infant radiant warmers (as per 80 FMT, CFR §880.5130) containing an infrared heating element mounted above a built-in pediatric bed assembly, in order to maintain an infant's body temperature by means of controlled radiant heat.

The IW960 and IW970 are designed to provide warmth to babies in the first few weeks of life, when an infant's self-thermoregulation capacity may be reduced, or if external thermal support is required or desirable. This may include new-born babies in delivery room applications, including premature / low birth-weight infants, and support of critically ill babies in neonatal intensive care units (NICU's) or special care baby units (SCBU's). Situations which necessitate unobstructed access to an infant, including during resuscitation or surgical procedures, may indicate the need for a radiant heat source instead of equivalent support devices such as infant incubators.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972885

Prescription Use ✓
(Per 21 CFR §801.109)