K971366

510(k) Summary

JAN - 5 1998

April 11, 1996

Applicant:

Hill-Rom, Inc.
1069 St. Route 46 East
Batesville, IN 47006
Reg. No: 1824206

Contact Person:

James G. Carpenter
Ph: (812)934-1671
Fx: (812)934-1675

Device trade/proprietary name:

IncuWarmer

Device common/usual/classification name:

Infant Radiant Warmer

Classification:

General Hospital and Personal Use Device, 21 CFR 880.5130 , Infant Radiant Warmer, 80FMT, Class III

Performance Standards:

21 CFR Part 1020, "Performance Standard for Ionizing Radiation Emitting Products"

Predicate (Current) Device:

Resuscitaire® Radiant Warmer, K940951
ISOLETTE® Infant Incubator, K960980
Care Plus Infant Incubator, K943360
Stabilet™ Infant Radiant Warmer, K970074

Device Description

The IncuWarmer is a warming device that combines the heating technologies of both incubators and radiant warmers into one product. The IncuWarmer provides thermal isolation primarily through a convective air system with canopies and side panels to form an enclosure that isolates the air surrounding the infant from the room air. The IncuWarmer offers access to the infant by allowing the cargiver to open port holes, side panels, canopies, and, if more access is needed, raising up of the over head arm. The over head arm is the upper half of the infant enclosure containing the canopies. The over head arm can be is raised to obtain full access to the infant. The over head arm contains two tubular stainless steel infrared heaters that provide supplementary heat when the canopies and side panels are closed and primary heat when the canopies are opened or the over head arm is raised.

In addition to providing thermal support, the IncuWarmer is capable of controlling options and accessories to aid the caregiver in rendering care to the infant. The IncuWarmer accessories are designed to operate with the IncuWarmer and consist of a humidification accessory, phototherapy accessory, and scale accessory for weighing the infant.

Intended Use:

The IncuWarmer is a mobile,caster mounted, neonatal device which is used to assist in maintaining an infant's skin temperature and thermal environment. The device accomplishes this through the use of radiant and convective heat. Accessories and options to the device permit environmental control and monitoring including phototherapy capability, scale, and humidification. It is intended for in-patient use in maternity nurseries, and neonatal care environments of hospitals or other healthcare facilities.

Design and Construction:

Both the new and predicate device(s) utilize the same materials and methods of construction. They are fabricated from steel, aluminum, and plastic. The new device's most highly stressed areas utilize only steel and aluminum. Plastics are used in less stressed areas. Steel and aluminum components are welded or assembled with commercially available fasteners. Plastics used in less stressed areas are assembled with fasteners.

The new device electronics are controlled by a microprocessor as are the predicate devices except the Hill-Rom Stabilet™. The Stabilet™ uses an analog control system. The differences in the control systems are transparent to the user.

The subject device and predicate device(s) in this submission are substantially equivalent. All issues concerning the safety and effectiveness of the IncuWarmer are addressed in the design, labeling , and manufacture of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 1998

Mr. James G. Carpenter
Manager, Regulatory Affairs
Hill-Rom, Incorporated
1069 State Route 46E
Batesville, Indiana 47006-9167

Re: K971366
Trade Name: IncuWarmer
Regulatory Class: II
Product Code: FMT
Dated: October 3, 1997
Received: October 7, 1997

Dear Mr. Carpenter:

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

Indications for Use

510(k) Number: Unknown

Device Name: IncuWarmer®

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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)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971366

Prescription Use —X— OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1/2/96)