

FEB 3 2000

510(k) Summary

September 09, 1999

K993051

Applicant:

Hill-Rom Air-Shields
330 Jacksonville Road
Hatboro, PA 19040
Reg. No: 2510954

Contact Person:

James G. Carpenter
Ph: (215) 675-5200
Fx: (215) 682-8689

Device trade/proprietary name:

Versalet™ 7700 Care Center

Device common/usual/classification name:

Infant Incubator

Classification:

General Hospital
21 CFR 880.5400
Incubator Neonatal, FMZ, Class II

Performance Standards:

None applicable.

Predicate (Current) Device:

Hill-Rom Air-Shields Resuscitaire® Radiant Warmer,	K940951
Hill-Rom Air-Shields ISOLETTE® Infant Incubator,	K960980
Hill-Rom Incuwarmer	K971366
Dräger Babytherm 8004 Babytherm 8010	K971198

Device Description

The Versalet™ 7700 Care Center is a warming device that combines the heating technologies of both incubators and radiant warmers into one product. The Versalet™ 7700 Care Center 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 Versalet™ 7700 Care Center offers access to the infant by allowing the caregiver 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 Calrod (Magnesium oxide encased in Incoloy sheath) heaters that provide heat when the canopies are opened or the over head arm is raised.

In addition to providing thermal support, the Versalet™ 7700 Care Center is capable of controlling options and accessories to aid the caregiver in rendering care to the infant. A humidification accessory is designed to operate with the Versalet™ 7700 Care Center.

Intended Use:

The Versalet™ 7700 Care Center is a mobile, caster mounted, neonatal device that 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 to the device permit environmental control and monitoring including 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.

The subject device and predicate device(s) in this submission are substantially equivalent. All issues concerning the safety and effectiveness of the Versalet™ 7700 Care Center are addressed in the design, labeling, and manufacture of the device.



FEB 3 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Larryl W. Krasley
Regulatory Affairs Specialist
Hill-Rom Air-Shields
330 Jacksonville Road
Hatboro, Pennsylvania 19040

Re: K993051
Trade Name: Versalet 7700 Care Center Model 7700
Regulatory Class: II
Product Code: FMZ
Dated: January 6, 2000
Received: January 7, 2000

Dear Mr. Krasley:

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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

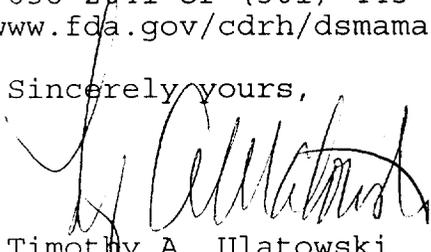
Page 2 - Mr. Krasley

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) 594-4692. 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 K993051

Device Name: Versalet 7700 Care Center

Indications for Use:

The Versalet 7700 Care Center 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 using radiant and convective heat. Accessories and options to the device permit environmental control and monitoring including humidification. It is intended for in-patient use in maternity nurseries, and neonatal care environments of hospitals or other healthcare facilities.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1/2/96)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number 993051