K971243

Ohmeda Infant Resuscitation System
510(k) Summary

DEC - 2 1997

1. Predicate Device Information

The IRS is a combination of the following stand-alone medical devices:

- Ohio Pressure Compensated Flowmeter - 510(k) No. K760102
- Ohio Continuous Suction Regulator (wall vacuum powered) - 510(k) No. K883229
- Ohio Continuous Suction Regulator (venturi powered) - Substantially equivalent to the wall vacuum powered configuration
- Ohmeda Oxygen Blender - 510(k) No. K853905
- Airway Manometer - Substantially equivalent to the Airway Manometer included in the resuscitation section of the Air Shields Resuscitaire™ (a Class II Infant Radiant Warmer)

In addition, the IRS is substantially equivalent to the resuscitation sections of the Hill Rom Stabilet 2000C Infant Warmer and to the Air Shields Resuscitaire™ Radiant Warmer.

2. Intended Use Statement

The Infant Resuscitation System provides the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen and/or manual ventilation to the infant. These practices are well-described in collaborative guidelines established by the American Heart Association and the American Academy of Pediatrics.

Resuscitation may be required whenever an infant fails to establish effective, adequate breathing patterns necessary to meet tissue oxygen demands and/or to rid the body of carbon dioxide.

3. Functional Description

The Infant Resuscitation System incorporates a suction device for routine clearance of mucous and debris from the trachea and nasal passages, as well as one oxygen flowmeter for delivery of oxygen to the infant requiring such therapy. The airway pressure manometer is attached to a resuscitation bag (not included) and measures the pressure delivered to the infant in order to facilitate adequate pressurization of the lungs. An optional gas blender mixes air and oxygen in percentages selected by the user. The Infant Resuscitation System includes hoses to connect the system to wall or cylinder outlets and/or assemblies. It does not include the resuscitation bag for manual ventilation.

4. Assessment of Technological Characteristics

The technological characteristics of the IRS are similar to those of the predicate devices to which the IRS is substantially equivalent. The IRS is a combination of devices which are either preamendment devices or have been cleared for commercial distribution via Premarket Notification.

5. Performance Data

Pulmonary resuscitation of infants includes well established clinical practices. These practices are well-described in collaborative guidelines established by the American Heart Association and the American Academy of Pediatrics. The IRS provide clinicians with the means to implement these practices. Consequently, clinical testing to demonstrate safety and effectiveness is not required. Bench testing will be conducted to ensure that the device meets its specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 1997

Mr. Alberto F. Profumo
Ohmeda, Inc.
9065 Guilford Road
Columbia, Maryland 21046-1801

Re: K971243
Ohmeda Infant Resuscitation System ("IRS")
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: September 4, 1997
Received: September 8, 1997

Dear Mr. Profumo:

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 requirements, 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) 594-4648. 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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971213

Device Name: Infant Resuscitation System

Indications For Use:

Clinical Use Description
Infant Resuscitation System

The Infant Resuscitation System provides the basic equipment required for pulmonary resuscitation during infancy. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen and/or manual ventilation to the infant. These practices are well-described in collaborative guidelines established by the American Heart Association (AHA) and the American Academy of Pediatrics (AAP).

Resuscitation may be required whenever an infant fails to establish effective, adequate breathing patterns necessary to meet tissue oxygen demands and/or to rid the body of carbon dioxide.

The Infant Resuscitation System incorporates the following features for the practice of infant resuscitation: a suction device for routine clearance of the trachea and nasal passages; an oxygen flowmeter to deliver 100% oxygen to the infant requiring such therapy; and an airway pressure manometer with an adjustable pressure relief valve (12-55 cm H2O). The airway pressure manometer may be attached to a resuscitation bag (not included) and is used to measure the pressure being delivered to the infant in order to facilitate adequate pressurization of the lungs. An adjustable pressure relief valve is a safety feature which helps prevent the user from over-inflating the infant's lungs, which could result in rupture of the alveoli. The valve may be adjusted to release excess gas at a user selected pressure point. The ability to adjust the pressure relief valve facilitates optimal oxygen delivery as lung compliance changes dynamically after birth during the transition to extrauterine life. The operative range (12-55 cm H2O) of this feature meets the recommendations by the AHA and AAP. The Infant Resuscitation System is outfitted with unregulated air and oxygen outlet connection which may be attached to an optional gas blender for the purposes of delivering air and oxygen mixes in the user selected percentages. The Resuscitation System may be equipped with optional hoses to connect the system to wall or cylinder outlets and/or yoke assemblies.

The Infant Resuscitation System does not include the resuscitation bag for manual ventilation.

(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)

Over- The Counter Use ____

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

(Optional Format 1-2-96)