K070247

510(k) Summary

Submitter Information and Date Prepared

Mary Dadone
GE Healthcare
8880 Gorman Road
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USA

410-888-5327

APR 20 2007

Prepared January 24 2007

Device Identification

Proprietary Name: Giraffe and Panda Bag and Mask Resuscitation System
Common Name: Manual Emergency Ventilator (Resuscitator)
Classification Name: Manual emergency ventilator (21 CFR 868.5915)

Predicate Device Information

The Giraffe and Panda Bag and Mask Resuscitation System is substantially equivalent to the following predicate devices:

Predicate Device	Last 510(k) Number
Ohmeda Medical Infant Resuscitation System	K971243
AirShields Resuscitaire	K003335
Atom InfaWarmer V505	K002355

Intended Use Statement

The Bag and Mask 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 or air/oxygen mixtures and/or manual ventilation to the infant. These are clinical practices that represent the established standard of care.*

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.

For professional use only, by trained clinicians.

* As stated in collaborative guidelines written by the American Heart Association (AHA) and the American Academy of Pediatrics (AAP) in the Textbook of Neonatal Resuscitation, 5th Edition.

Functional Description and Technological Characteristics

The Bag and Mask Resuscitation System incorporates the following features for the practice of infant resuscitation: a suction device for clearance of the trachea and nasal passages; an optional air/oxygen blender including high-pressure yokes that allows the clinician to adjust FiO2 % from 21-100%; two medical gas flowmeters to deliver oxygen or air/oxygen mixtures to the infant requiring such therapy; and an airway pressure manometer.

The airway pressure manometer allows a trained clinician to see pressure throughout the respiratory cycle.

Peak Inspiratory Pressure (PIP) is adjusted using the PIP knob located on the front panel of the resuscitation system that allows the clinician to set the maximum pressure being delivered to the infant in order to facilitate adequate pressurization of the lungs.

The Giraffe and Panda Bag and Mask Resuscitation System, like the Ohmeda Medical Infant Resuscitation System, does not include the manual resuscitator. The patient circuit is to be supplied by the user.

Performance Data

Pulmonary resuscitation of infants includes well established clinical practices; animal or clinical testing to support safety and effectiveness is not necessary. The conformance of the Giraffe and Panda Bag and Mask Resuscitation System to performance specifications and to multiple recognized performance standards is being established through bench testing.

Prepared by: Mary Dadian Date 24 Jan 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 2007

Ms. Agata Smieja
Global Compliance Leader
Maternal Infant Care, Clinical Systems, GE Healthcare
8880 Gorman Road
Laurel, Maryland 20723

Re: K070247
Trade/Device Name: Giraffe and Panda Bag and Mask Resuscitation System
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: II
Product Code: BTM
Dated: March 30, 2007
Received: April 2, 2007

Dear Ms. Smieja:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

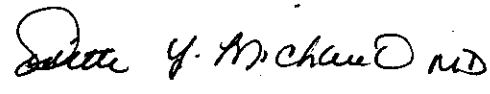
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Giraffe and Panda Bag and Mask Resuscitation System

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]

[illegible] Control, [illegible] Devices

(K) Number K070247