MAR 2 4 2000

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Substantial Equivalence 510(k)Summary

Rusch Manual Resuscitator Bag

To Whom it may concern **Ref: K993194**

Date: September 17th 1999

Submitter/ Contact - Name and Address

Ronald J. Young
Director, Manufacturing Operations
Rusch Inc.
2450 Meadowbrook Parkway
Duluth, GA 30096

Telephone: (770) 623-0816
Fax: (770) 623-1829

Device Details:

Common/ Usual Name: Rusch Manual Resuscitator Bag

Classification Name: Manual Emergency Ventilator (Resuscitator)

Predicate Legally Marketed Device: Baxter Adult/ Pedi/ Infant Resuscitator Bag: K924610

DESCRIPTION OF THE DEVICE

The product consists of a face mask, bag, valve, reservoir bag, and tubing with connector for introduction of oxygen enriched air. The valve is made from K-Resin and the other main components mentioned above are made from PVC.
The cushion mask is clear to permit easy patient monitoring and is mounted on a 360° swivel for convenience. The bag is textured to give a positive grip.

INTENDED USE

The manual resuscitator is intended for use on patients requiring total or intermittent airway support. Provides positive pressure ventilation and allows spontaneous breathing either with a 22mm inner diameter face mask port or through an artificial airway having a 15mm outer diameter connection.

Technological Characteristics of the Device

The device is equivalent is design and construction to the Engineered Medical Systems Manual Resuscitator Bag

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 2000

Mr. Ronald Young
Rusch, Inc.
2450 Meadowbrook Parkway
Duluth, GA 30096

Re: K993194
Rusch Manual Resuscitator Bag
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: December 21, 1999
Received: January 10, 2000

Dear Mr. Young:

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 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). 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/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Response Page

510(k) Number (if known): K993194

Device Name: Rusch Manual Resuscitator Bag

Indications For Use:

The Rusch Manual Resuscitator is intended for manual ventilation of patients with air or air enriched oxygen The resuscitator is manufactured as either an adult, pediatric, or infant model, intended to treat an adult child, or infant respectively

(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 Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

(Optional Format 3-10-98)

PRESCRIPTION USE X OR OVER THE COUNTER USE ___