K993528

MAY 3 1 2000

(E1)

Attachment E

Substantial Equivalence 510(k)Summary

Rusch Emergency Mask

To Whom it may concern

Date: October 14, 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:

Trade Name: Rusch Emergency Mask

Common Name: Emergency CPR Mask

Classification Name: Mask, Oxygen, Non-Rebreathing

Predicate Legally Marketed Device: Laerdal Pocket Mask™ K933048

Intended Use

The Rusch Emergency Mask is designed to assist in providing immediate life support to health emergency victims requiring oxygen support (inhalation) or cardiopulmonary resuscitation (CPR) rescue techniques.

Description Of The Device

The Rusch Emergency Mask is one-piece, single use, full-sized light weight PVC mask system which includes a universal breathing tube, one way filtered valve, head straps and oxygen port. The design of the ER mask permits it to fold into a convenient pocket sized case for portability yet deploy instantly for use as a CPR Mask when removed from its package. The mask can be supplied with or without examination gloves.

The soft PVC cushion promotes a seal to the face allowing ventilation through both the mouth and nose simultaneously. The transparent structure permits visual identification. The mouth piece and the one way valve with 3M Filtrate ™ filter provide the rescuer protection when using "mouth-to-mouth" rescue techniques. The proximal end of the breathing tube can be attached to a universal resuscitation bag port while the integral oxygen tube allows for connection to an emergency oxygen system.

Technological Characteristics of the Device

The device is equivalent is design and construction to the Laerdal Pocket Mask™ K933048

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2000

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

Re: K993528
Rusch Emergency Mask
Regulatory Class: II (two)
Product Code: 73 CBP
Dated: May 9, 2000
Received: May 15, 2000

Dear Mr. Young:

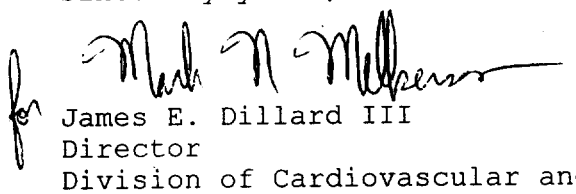
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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,



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

Enclosure

510(k) Number (if known): _____

Device Name: Rusch Emergency Mask

Indications For Use:

The Rusch Emergency Mask is designed to assist in providing immediate life support to health emergency victims requiring oxygen support(inhalation) or cardiopulmonary resuscitation (CPR) rescue techniques. The device is intended for mouth to mask ventilation by trained individuals trained in the use of the device and qualified to use the device. The device is intended to be used on adult,child and infant population.

Signed

Director Manufacturing Operations

Date 01/19/00

(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 K993538/

✓ prescription use

(Optional Format 3-10-98)