K014115

FEB 2 7 2002

Portex, Inc.
10 Bowman Drive
Keene NH 03431-0724 USA
Tel: 603 352 3812
www.portexusa.com

K: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY:

COMPANY INFORMATION:

Portex Inc
10 Bowman Drive
Keene, NH 03431
(603) 352-3812
Contact: Timothy J. Talcott
Director of Regulatory Compliance

PREPARATION DATE OF SUMMARY:

December 12, 2001

TRADE NAME:

1st **Response** Manual Resuscitator

COMMON NAME:

Manual Resuscitator

PRODUCT CLASS/CLASSIFICATION:

Class II, 73 BTM, 21 CFR 868.5915

PREDICATE DEVICE(S):

Portex, Inc., Ft. Myers Florida, 1st **Response** Manual Resuscitators, Cat. No. 008000, 008003, and 008006, (K992057).

DESCRIPTION:

The 1st **Response** manual resuscitator is a disposable, single use emergency manual ventilator. It is intended for single patient use only.

Each device consists of a plastic compressible ventilator bag fitted with control valves at each of the two ends. The inlet valve, opposite the patient end, allows entry of fresh gas into the compressible ventilator bag. The valve blocks escape of fresh gas from the ventilator bag during its compression. Attached to this valve are one of three types of reservoirs; bag reservoir, expandable tube reservoir, or flexible length tube reservoir. These reservoirs serve to collect an overflow of oxygen when a supplemental oxygen supply is used.

The patient end of the ventilator bag is fitted with a second valve assembly. This valve consists of a 15 mm ID x 22 mm OD patient connector and exhalation port. The patient port has a swivel feature to allow the care provider to move the bag around the patient, as needed.

Standard configurations of the device are provided with or without a breathing mask and with or without a PEEP valve. Special configurations are available which could include; pre-attached components, exhalation filter, varying lengths of oxygen lines, varying sizes of breathing masks, and oropharyngeal airways (Berman and Guedel).

The breathing mask consists of a clear flexible cone that features a 22 mm ID port and a clear tacky cushion that contacts the patient's face. The PEEP valve features a 30 mm ID port and a knob to allow the care provider the ability to adjust the amount of PEEP. The PEEP valve can be adjusted from 5-20 cm H_2O and uses two springs and a silicone rubber diaphragm to regulate the exhaust pressure.

INDICATIONS FOR USE:

The 1st **Response** Manual Resuscitator is a pulmonary-assist device intended to provide respiratory support to patients suffering from respiratory distress. It is intended for use on patients with a body mass of 25 kg (55 lbs) or more.

TECHNICAL CHARACTERISTICS:

The device has the same technical characteristics as the device we have authorization to market under premarket notification K992057.

NON-CLINICAL DATA:

Performance and specifications of the modified device are consistent with all requirements for this device type specified by: ASTM 920; Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans, ISO 8382:1988 (E) Resuscitators intended for use with humans, and ISO 5356-

1: 1987 – Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets.

CONCLUSION:

The comparison to the predicate device demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

PORTEX, INC.

Timothy J. Talcott
Director of Regulatory Compliance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2002

Mr. Timothy J. Talcott
Portex, Inc.
10 Bowman Drive
Keene, NH 03431-0724

Re: K014115
1st Response Manual Resuscitator
Regulation Number: 868.5915
Regulation Name: Ventilator, Emergency Manual (Resuscitator)
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: December 12, 2001
Received: December 14, 2001

Dear Mr. Talcott:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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 Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B: INTENDED USE OF DEVICE

PROPOSED INDICATIONS FOR USE:

510(k) Number (if known): ~~Unknown~~ K014115

Device Name: **1st Response** Manual Resuscitator

Indications For Use:

The **1st Response** Manual Resuscitator is a pulmonary-assist device intended to provide respiratory support to patients suffering from respiratory distress. It is intended for use on patients with a body mass of 25 kg (55 lbs) or more.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014115

Prescription Use ✓ OR Over-The-Counter Use _____