SEP | 3 1999

K992057

SIMS SMITHS INDUSTRIES
Medical Systems

SIMS Portex Inc.
10 Bowman Drive
PO Box 0724
Keene NH 03431 USA
Telephone: 603-352-3812
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J: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY:

COMPANY INFORMATION:

SIMS Portex Inc
10 Bowman Drive
Keene, NH 03431
(603) 352-3812
Contact: Timothy J. Talcott
Manager, Regulatory Affairs

PREPARATION DATE OF SUMMARY:

June 16, 1999

TRADE NAME:

1st Response Manual Resuscitator

COMMON NAME:

Manual Resuscitator

PRODUCT CLASS/CLASSIFICATION:

Class II, 73 BTM, 21 CFR 868.5915

PREDICATE DEVICE(S):

SIMS Portex Inc., Ft. Myers Florida, **1st Response** Adult Manual Resuscitators, Cat. No. 008000, 008003, and 008006.

Laerdal Medical Corporation, Wappingers Falls, New York, Laerdal Silicone Resuscitator, Adult.

DESCRIPTION:

The 1st Response manual resuscitator is a disposable, single use emergency manual ventilator. 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 two types of reservoirs; bag reservoir or 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. A manometer port is optional.

The device is provided with or without a facemask. Special configurations are available which include a disposable manometer, PEEP valve with adapter, or exhalation filter.

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 20 kg (44 lbs) or more.

TECHNICAL CHARACTERISTICS:

The device has the same technical characteristics as the device we have authorization to market under premarket notification K972283.

NON-CLINICAL DATA:

Performance and specifications of the modified device are consistent with all requirements for this device type specified by 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 devices demonstrate that the proposed device is safe and effective and is substantially equivalent to the predicate devices.

Very truly yours,

SIMS PORTEX INC.

Timothy J. Talcott
Manager, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 1999

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

Re: K992057
1st Response Adult Manual Resuscitator
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: June 16, 1999
Received: June 18, 1999

Dear Mr. Talcott:

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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological 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): K992057

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)

Prescription Use ✓ OR Over-The-Counter Use _____

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

510(k) Number _____