K073410

5. 510(k) Summary

SEP 1 2 2008

Submitting Information:

510(k) Owner's Name	ArtiVent Corporation
Address	270 Frederick Street No. 2 San Francisco, CA 94117
Phone Number	415-759-8400
Fax Number	415-759-8493
Contact Person	Grace Holland
Company	Regulatory Specialists, Inc.
Contact Address	3722 Ave. Sausalito Irvine, CA 92606
Contact Phone	949-262-0411
Date	November 30, 2007

Device Information:

Trade Name	SAVe™ Resuscitator
Common Name	Manual resuscitator
Classification Name	Ventilator, Emergency, Manual (Resuscitator)
CFR Reference	868.5915
Product Code	BTM

Predicate Information:

K #	Predicate Name	Submitter
K023793	1st Response Intermediate Manual Resuscitator	Portex Inc.
K053140	Ambu Mark IV Resuscitator	Ambu Corp.

Device Description:

The SAVe™ Manual Resuscitator is a hand operated resuscitator that provides control of the volume of delivered ventilation gas (air or oxygen-enriched gas).

Indications for Use:

The SAVe™ Resuscitator is intended for manual pulmonary resuscitation and emergency respiratory support. SAVe Resuscitator is intended for patients with a body mass of more than 15kg (~33 lbs), approx. 3 years of age.

Summary of the technological characteristics of our device compared to the predicate devices:

The SAVe™ Resuscitator differs from the predicates, K053140, Ambu Mark IV Resuscitator and K023793, 1st Response Intermediate Manual Resuscitator in that it has an adjustable volume control.

The SAVe™ Resuscitator is substantially equivalent to the predicates, K053140, Ambu Mark IV Resuscitator and K023793, 1st Response Intermediate Manual Resuscitator in the following respects:

* indications for use
* target population
* anatomical sites
* where used (hospital, home, ambulance, etc)
* energy used and/or delivered
* design
* performance
* standards met
* materials
* biocompatibility
* compatibility with the environment and other devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2008

ArtiVent Corporation
C/O Ms. Grace Holland
Regulatory Specialist
Regulatory Specialist, Incorporated
3722 Avenue Sausalito
Irvine, California 92606

Re: K073410
Trade/Device Name: SAVe Resuscitator
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: II
Product Code: BTM
Dated: September 8, 2008
Received: September 9, 2008

Dear Ms. Holland:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Enclosures

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K073410

Device Name: SAVe Resuscitator

Indications for Use:

The SAVe™ Resuscitator is intended for manual pulmonary resuscitation and emergency respiratory support.
SAVe™ Resuscitator is intended for patients with a body mass of more than 15kg (~33 lbs), approx. 3 years of age.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073410