DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 3, 2016

The Lifeguard Store, Inc.
% Jennifer J. Hennessy
Attorney
Quarles & Brady, Llp
33 E Main Street, Suite 900
Madison, Wisconsin 53703

Re: K152521
Trade/Device Name: Seal Rite Non-Rebreathing Valve
Regulation Number: 21 CFR 868.5870
Regulation Name: Nonrebreathing Valve
Regulatory Class: Class II
Product Code: CBP
Dated: May 4, 2016
Received: May 5, 2016

Dear Jennifer J. Hennessy:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152521

Device Name

Seal Rite Non-Rebreathing Valve

Indications for Use *(Describe)*

The Seal Rite Non-Rebreathing Valve is a single-use, non-sterile device intended to be used with a ventilation mask (without oxygen port) to provide mouth-to-mask ventilation to health emergency victims requiring cardiopulmonary resuscitation ("CPR") rescue techniques. It is intended for over-the-counter use.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Seal Rite™ Non-Rebreathing Valve 510(k) Summary

K152521

Premarket Notification (510(k)) Number

Submitter's Name	The Lifeguard Store, Inc. 2012 W. College Ave. Normal, IL 61761 Telephone: (309) 451-5858 Fax: (309) 451-5959
Registration Number	3003197958
Contact Name	Amy Hilten, COO The Lifeguard Store, Inc. 2012 W. College Ave. Normal, IL 61761 Telephone: (309) 451-5858 Fax: (309) 451-5959 Email: amy@thelifeguardstore.com
Date Prepared	June 2, 2016
Device Trade Name	Seal Rite™ Non-Rebreathing Valve
Device Common Name	Non-Rebreathing Valve
Classification Name	Valve, Non-Rebreathing
Product Code	CBP
Device Classification	Class II
Panel	Anesthesiology and Respiratory Devices
Regulatory Classification	21 CFR 868.5870
Type of 510(k) Submission	Traditional
Legally Marketed Predicate Device	Respironics Rescue Valve (K833748)

Description

The Seal Rite™ Non-Rebreathing Valve ("Seal Rite Valve") is a resuscitation valve designed for resuscitation using expired air for ventilation. It has fittings on the grooved patient end that will adapt to standard masks (22 mm ID) used for resuscitation. The Seal Rite Valve allows the rescuer to blow air into a mask through its silicone one-way valve and directs the patient's exhaled air away from the rescuer via a rigid one-way valve and multiple exhaust ports. The Seal Rite Valve helps protect the rescuer from potential patient contamination. The Seal Rite Valve does not have an oxygen port.

Indications for Use

The Seal Rite Non-Rebreathing Valve is a single-use, non-sterile device intended to be used with a ventilation mask (without oxygen port) to provide mouth-to-mask ventilation to health emergency victims requiring cardiopulmonary resuscitation ("CPR") rescue techniques. It is intended for over-the-counter use.

Predicate Device

The Seal Rite Valve is substantially equivalent to the Respironics Rescue Valve (K833748). The Seal Rite Valve and the Rescue Valve are both resuscitation valves utilized for mouth-to-mask emergency resuscitation using expired air from the rescuer through a valve for ventilation of the patient. Both valves direct the patient's exhaled gases away from the rescuer's face via a rigid one-way valve, and both valves have an ISO Standard 15/22 connector that allows use with a standard mask.

Please refer to the Substantial Equivalence Summary Comparison Table below for a summary of the similarities and differences between the subject and predicate devices.

Description of Operation

The Seal Rite Valve consists of a plastic body with two one-way valves: a silicone inspiratory one-way valve and a rigid, plastic expiratory one-way valve. Rescuers utilizing the Seal Rite Valve place their lips on the open end of the valve and blow expired air into the valve, which is attached to a standard mask, for the purpose of supplying rescue breaths to the patient. When the expired air enters the top of the Seal Rite Valve, the rigid one-way valve moves toward the patient, seals multiple exhaust ports, and the silicone one-way valve opens and provides air from the rescuer to the patient. The rigid, plastic expiratory valve remains closed when the rescuer is providing exhaled air to the patient because the pressure on the rescuer side of the plastic valve is

greater than the pressure inside the patient's airways. When the rescuer stops breathing exhaled air into the Seal Rite Valve, the silicone one-way valve closes and prevents the backflow of exhaled air from the patient to the rescuer. The rigid, plastic one-way valve lifts off of the exhaust ports due to the pressure inside the patient's airways being greater than the atmospheric pressure. The patient's exhaled air passes then through multiple exhaust ports.

Technological Characteristics Summary

The Seal Rite Valve is substantially equivalent to the Respironics Rescue Valve (K833748) with respect to intended use, design, principle of operation, technological characteristics and performance and the minor difference in device materials does not raise new questions of safety or effectiveness.

The Seal Rite Valve was tested to ensure conformance with the FDA Recognized AS 4259-1995 standard ("Ancillary devices for expired air resuscitation") and passed all testing requirements.

Substantial Equivalence Summary Comparison Table

Features	**Seal Rite™ Non-Rebreathing Valve (K152521)**	**Respironics Rescue Valve (Predicate Device -- K833748)**
Intended Use	Mouth-to-mask ventilation	Mouth-to-mask ventilation
Product Code	CBP	CBP
Target Population	Adult/pediatric patients greater than 18 months of age	Adult/pediatric patients greater than 18 months of age
Environment of Use	Hospitals and field emergency	Hospitals and field emergency
Materials	Polycarbonate, silicone	Thermoplastic, silicone
Oxygen Port	Not available	Not available with standalone valve; option available only with accessory adapter cleared under K842693
Expiratory Resistance	0.327 cm H_2O (0.0321 kPa) at 50 LPM	0.25 cm H_2O at 50 LPM (per K142402 510(k) Summary)
Inspiratory Resistance	1.15 cm H_2O (0.113 kPa) at 50 LPM	1.85 cm H_2O at 50 LPM (per K142402 510(k) Summary)
Inlet Connector	Standard 22 mm ID	Standard 22 mm ID
Outlet Connector	Standard 22 mm OD/15 mm ID	Standard 22 mm OD/15 mm ID
Sterile	No	No
Reusable	No – single patient use device	No – single patient use device
Duration of Use	Less than 24 hours	Less than 24 hours

Principle of Operation	Air flow through device used to deliver inspiratory air and exhaled expiratory air from patient	Air flow through device used to deliver inspiratory air and exhaled expiratory air from patient
Compatibility	Designed for use with standard resuscitation masks	Designed for use with standard resuscitation masks

Performance Testing

As described below, a comprehensive battery of non-clinical tests was submitted to confirm product conformance with device requirements, including the FDA recognized AS 4259-1995 standard. These studies demonstrate that the Seal Rite™ Non-Rebreathing Valve is biocompatible, performs as intended and meets the requirements of the AS 4259-1995 standard and is therefore as safe and effective as the predicate device, the Rescue Valve.

Biocompatibility Testing

The biocompatibility testing was conducted in accordance with FDA Blue Book Memo G95-1. Testing was conducted for cytotoxicity, sensitization and irritation per ISO 10993-5, 10993-10 and 10993-12.

Test	Test Results
Cytotoxicity	Pass
Irritation	Pass
Sensitization	Pass

Bench Testing

Test	
Ventilation Performance	Pass
Expiratory Resistance for the Patient	Pass
Expiratory Resistance for the Rescuer	Pass
Inspiratory Resistance for a Spontaneously Breathing Patient	Pass
Function After Contamination with Stomach Contents	Pass

Function After Immersion in Water	Pass
Measurement of Dead Space	Pass
Resistance to Disengagement of Parts	Pass
High and Low Storage Conditions	Pass
High Temperature Operation	Pass
Low Temperature Operation	Pass
Attempted Displacement of Valve by Finger, Function After Dropping, Function After Potentially Deforming Weight	Pass
Conformance of Connectors	Pass
ISTA Procedure 2A Shipping Testing	Pass

In summary, the Seal Rite Valve is substantially equivalent to the predicate Respironics Rescue Valve with respect to intended use, technological characteristics and performance.