January 18, 2018

International Biomedical
Amy Pieper
Director of Regulatory Affairs
8206 Cross Park Drive
Austin, Texas 78754

Re: K182956
Trade/Device Name: Puffin Lite Infant Resuscitation System
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: Class II
Product Code: BTL
Dated: December 19, 2018
Received: December 19, 2018

Dear Amy Pieper:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee -S

for Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182956

Device Name
Puffin Lite Infant Resuscitation System

Indications for Use *(Describe)*
The Puffin Lite Infant Resuscitator is intended to provide the basic equipment required for pulmonary resuscitation of neonatal infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the neonatal infant.

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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510(k) SUMMARY

Submitter Information:

International Biomedical
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U.S.A.

Regulatory Affairs Contact:

Amy Pieper
Director of Regulatory Affairs
(512) 873-0033 - phone
(512) 873-9090 - fax

Date Summary Prepared: January 8, 2019

Device Identification:

Trade Name: Puffin Lite Infant Resuscitation System

Common Name: Ventilator, Emergency Gas Powered (Resuscitator)

Regulatory Class: II

Regulation: 868.5925

Product Code: BTL

Panel: Anesthesiology

Predicate Device:

LifeBorne Infant Resuscitator, International Biomedical, k140707

Device Description:

The resuscitation system provides the basic equipment required for pulmonary resuscitation of neonatal infants. The Puffin Lite Infant Resuscitator is a gas powered emergency resuscitation system. It is intended to be used inside the hospital by trained medical professionals to provide precise FIO2 delivery, and manual ventilation as established by resuscitation guidelines to neonatal infants weighing less than 10 kg (22 lb).

The resuscitation system includes two medical gas flowmeters, an integrated oxygen blender, airway pressure manometer, peak inspiratory pressure (PIP) control, positive end expiratory pressure (PEEP) control, a gas supply pressure alarm and T-piece resuscitator.

Modifications from the predicate device were:

- The integrated venturi suction portion was removed from the LifeBorne Infant Resuscitation System to create the Puffin Lite Infant Resuscitation System.
- The overall form-factor was reduced (based on the removal of the suction function and the redundant air and oxygen gas inputs)
- Changes made to the device did not impact delivery of flow, pressure or waveform delivered to the patient

Indications for Use:

The Puffin Lite Infant Resuscitator is intended to provide the basic equipment required for pulmonary resuscitation of neonatal infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the neonatal infant.

Functional Description and Technological Characteristics:

The Puffin Lite Infant Resuscitation System incorporates the following components for neonatal resuscitation, all of which are unchanged from the predicate device:

- Medical blender to mix air and oxygen to a precise FIO2 (K883038 or K925982, also part of K140707 submission)
- Flowmeters for the delivery of oxygen or air/oxygen mixtures (included in K140707 submission)
- Peak Inspiratory Pressure (PIP) control to set the maximum pressure delivered during an inspiratory phase of a manual breath (included in K140707 submission)
- Peak End Expiratory Pressure (PEEP) control located on a provided T-piece circuit to set the maximum pressure during the expiratory phase of a manual breath (K093913, also part of K140707 submission)
- An airway pressure manometer to monitor both PIP and PEEP airway pressure (included in K140707 submission)

Substantial Equivalence:

The Puffin Lite Infant Resuscitation System described in this submission is substantially equivalent to the predicate device, in regard to intended use. The intended use of the Puffin Lite Infant Resuscitation System is unchanged from the predicate device.

Changes made to the Puffin Lite versus the Puffin did not impact delivery of flow, pressure or waveform delivered to the patient. The Puffin Lite differs from the Puffin in that the venturi suction and the redundant air and oxygen inputs were eliminated. These changes allow for a smaller footprint that is easier to integrate. The airway portion of the Puffin Lite is identical to the predicate Puffin Infant Resuscitator. Calibration of the Puffin Lite airway is identical to the predicate Puffin device as all output parameters such as flow, peak inspiratory pressure (PIP) and fractional of inspired oxygen concertation (FIO_2) are the same. Because these output parameters have not changed, when the interface circuit is attached, flow, PIP and FIO_2 delivered to the patient does not change. Additionally, all pressure, flow and volume waveforms for the Puffin Lite are identical to its predicate device given the same compliance and resistance of the lung impacted.

	Proposed Puffin Lite Infant Resuscitator	LifeBorne Infant Resuscitator K140707
Indications for Use	The Puffin Lite Infant Resuscitator is intended to provide the basic equipment required for pulmonary resuscitation of neonatal infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the neonatal infant.	The LifeBorne Infant Resuscitator is intended to provide the basic equipment required for pulmonary resuscitation of neonatal infants. Pulmonary resuscitation includes practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures and/or manual ventilation to the neonatal infant.
Environment for Use	Hospital, delivery suites, nursery, ICU	Hospital, delivery suites, nursery, ICU
Patient Population	Neonatal Infant < 10 kg	Infant < 10 kg
Patient Connection	Face mask; ET tube	Face mask; ET tube
Air/Oxygen Mixture	21-100%	21-100%
Gas Flow Source	Wall gas or cylinder	Wall gas or cylinder
Manometer Range	-10 to 80 cm H2O	-10 to 80 cm H2O
Peak Inspiratory Pressure (PIP)	Max 45 +/- 5 cm H2O	Max 45 +/- 5 cm H2O
Positive End Expiratory Pressure	0-6 cm H2O	0-6 cm H2O

(PEEP)		
Vacuum Pressure Range	N/A – No Suction	0 – 150 mmHg, negative pressure
Maximum gas flow rate	15 LPM	15 LPM
Maximum pressure relief	55 cm H2O	55 cm H2O
Features: Venturi Vacuum Device	N/A – No Suction	Present
Features: Vacuum gauge	N/A – No Suction	Present
Features: Integrated Medical Blender	Present	Present
Features: Flowmeters for delivery of gas	Present	Present
Features: PIP control	Present	Present
Features: PEEP control	Present	Present
Features: Airway pressure manometer	Present	Present

Performance Testing:

Conformance of the Puffin Lite Infant Resuscitation System to performance specifications has been established through bench testing.

TEST	**TEST REQUIREMENTS**	**SUMMARY OF RESULTS**
Valve Function after Vomitus	The proper function of the circuit shall be verified within 20 seconds of becoming disabled by vomitus. Function is verified by verifying flow valve accuracy.	Passed.
Inspiratory Resistance	Pressure generated at the patient connection port during expiration should not exceed -5 cmH2O with inspiratory airflow set to 6 L/min.	Passed.
Expiratory Resistance	Pressure generated at the patient connection port during expiration should not exceed 5 cmH2O with expiratory airflow set to 6 L/min.	Passed.
Dead Space	The deadspace volume of the T-Piece circuit should be less	Passed.

	than 7 mL.	
FIO2 accuracy	The proper function of the FIO2 adjustment knob shall be verified by comparing the FIO2 setting value with the output oxygen concentration. Values shall be within 5%.	Passed.
Primary and Secondary Flow Valve – Peak Flow	The proper function of the primary and secondary flow valves shall be verified by comparing the flow setting with the actual measured output flow.	Passed.
Airway Manometer Accuracy	The proper function of the airway manometer shall be verified by comparing the pressure readings with the actual measured output pressure.	Passed.
VOC Testing	The device should not add volatile organic compounds (VOCs) to the output gas delivered to the patient.	Passed
Particulate Analysis	The output of particulate matter sizes 2.5 microns or less are no more than 12 micrograms/cubic meter of air at one atmospheric pressure.	Passed

The Puffin Lite Infant Resuscitator met all the performance requirements as outlined above and thus can be found to be substantially equivalent to the predicate device.

Conclusion:

The modified Puffin Lite Infant Resuscitator has the following similarities to the previous LifeBorne Infant Resuscitator that already has 510(k) clearance:

- The same intended use
- Use the same operating principle
- Incorporate the same basic design
- Incorporate equivalent materials (new materials were not introduced with the modification)
- No new features were added to the device
- The following features were removed from the predicate device to make the new, smaller, device: Integrated Venturi Suction, Redundant air/oxy inputs

The overall technology characteristics and performance are unchanged from the predicate device. Evaluation of the risks and performance data based on the differences between the subject and the predicate does not raise any new issues or concerns related to functionality of the device. Therefore, based on the submitted information in this premarket notification, the candidate device is substantially equivalent to the predicate device.