December 22, 2017

Advanced Circulatory System, a wholly owned subsidiary of ZOLL
Paul Dryden
Manager, Regulatory consultant for Advanced Circulatory System, a wholly owned subsidiary of ZOLL
c/o ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K172388
Trade/Device Name: VPOD™ Intrathoracic Pressure Regulator
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: August 6, 2017
Received: August 8, 2017

Dear Paul Dryden:

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.

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.

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,

Tina Kiang -S

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K172388

Device Name

VPOD™ Intrathoracic Pressure Regulator

Indications for Use *(Describe)*

The VPOD™ Intrathoracic Pressure Regulator is indicated for the temporary decrease in intrathoracic pressure to increase blood circulation, as prescribed by a physician, licensed practitioner, or qualified technician.

Recommended duration of use is up to four hours.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Page 1 of 7
22-Dec-17

Company:	Advanced Circulatory System a wholly owned subsidiary of ZOLL 1905 County Rd C West Roseville, MN 55113
Official Contact:	Anja Metzger, PhD VP, Research and Development and Grant Affairs Tel - 651.226.1626
Proprietary or Trade Name:	VPOD™ Intrathoracic Pressure Regulator
Common/Usual Name:	Intrathoracic Pressure Regulator
Classification Name:	21 CFR 868.5690 Procode – BWF Incentive spirometer Class II
Predicate Device:	K070490 – ACS CirQlator™

Device Description:
Advanced Circulatory Systems ("ACS") which is now part of Zoll, received clearance for the CirQlator™ Intrathoracic Pressure Regulator in 2007 under K070490. This device was developed to increase the return of venous blood back to the heart for treatment of a number of different clinical conditions associated with severe hypotension.

The predicate CirQlator Intrathoracic Pressure Regulator (ITPR) is used in combination with a positive pressure source such as a separate ventilator or manual resuscitation bag and an external vacuum source.

The proposed VPOD Intrathoracic Pressure Regulator (ITPR) is also intended to be used with patients who would benefit from increased venous return back to the heart for treatment of a number of different clinical conditions associated with severe hypotension but generates its own vacuum via the VPOD Motor and connects with a positive pressure source such as a separate ventilator or manual resuscitator bag.

Indications for Use:
The VPOD™ Intrathoracic Pressure Regulator is indicated for the temporary decrease in intrathoracic pressure to increase blood circulation, as prescribed by a physician, licensed practitioner, or qualified technician. Recommended duration of use is up to four hours.

Contraindications:
- persons with pneumothorax
- persons with hemothorax
- persons with hypertension
- persons with uncontrolled hemorrhage

Predicate Device Comparison

Table 1 – High Level Features and Differences

	Predicate CirQlator	**Proposed VPOD ITPR**
Vacuum source	External	Integrated – generated by VPOD Motor
Connects to separate positive pressure source	Yes	Yes
Fixed negative pressure	Yes -12 cmH_2O	Adjustable -2 to -12 cmH_2O

Table 2 – Comparison of Similarities

Features	**Predicate** **K070490** - CirQlator™	**Proposed** **VPOD™ ITPR**
Indications for use	The CirQlator™ Intrathoracic Pressure Regulator is indicated for the temporary decrease in intrathoracic pressure to increase blood circulation and blood pressure, as prescribed by a physician, licensed practitioner, or qualified technician. Recommended duration of use is up to four hours.	The VPOD™ Intrathoracic Pressure Regulator is indicated for the temporary decrease in intrathoracic pressure to increase blood circulation, as prescribed by a physician, licensed practitioner, or qualified technician. Recommended duration of use is up to four hours.
Environment of Use	Hospital, Pre-Hospital (EMS)	Same
Patient Population	Patients needing assisted ventilation that suffer from states of poor circulation, low blood pressure, or insufficient cardiac preload that may be reflected by low blood pressure.	Same
Contraindications	persons with pneumothorax persons with hemothorax persons with hypertension persons with uncontrolled hemorrhage	Same
Interfaces	Airway (Endotracheal tube, Combitube, facemask, laryngeal mask airway) Positive Pressure source (Manual resuscitator, anesthesia machine, ventilator) Vacuum source - external	Same Same No external vacuum source required; vacuum created by spinning impeller inside VPOD Blower.
Design	When connected to a vacuum source, this positive pressure breath results in mechanical movement of piston to allow patient to be ventilated, shutting off flow of vacuum. In between positive pressure breaths, vacuum path open which creates the negative intrathoracic pressure during the expiratory phase of ventilation.	VPOD Motor and Blower generate a vacuum. The Motor is magnetically coupled to the Blower. The Blower contains an impeller that when spun, creates a vacuum. In between the positive pressure breaths, the vacuum creates the negative intrathoracic pressure during the expiratory phase of ventilation.

Safety Valve	Silicone valve acts as a safety valve to ensure negative pressure does not exceed -9 mmHg	No external valving mechanism required. Microprocessor controlled blower continuously varies the negative intrathoracic pressure from -0.5 to -9 mmHg (-2 to -12 cmH_2O). This pressure is continuously monitored by microprocessor and the pressure sensors in the Motor. Any out of range performance (greater than -9 mmHg) will cause the Motor to shut down resulting in the discontinuation of the negative pressure. When blower is not spinning (In Standby Mode), there is no effect on airway pressure.
Safety Feature	Patient can breathe through device while device is attached to mask or endotracheal tube	Same
Vacuum level	Same for safety valve on device. Vacuum is primarily regulated by commercially available regulator placed at vacuum source	VPOD employs a miniature microprocessor controlled and monitored blower. Within the VPOD blower, three high-stability airway pressure sensors monitor ventilator and patient pressures, and each other, to ensure that the speed of the blower and the resultant pressure are within safety limits and that the single patient use blower and the motor are within safe temperature limits. Multiple alarm conditions (see hazards analysis table) will cause the blower to stop spinning and allowing breathing gasses to pass freely.
Patient status	Requires assisted ventilation	Requires assisted ventilation

Features	**Predicate** **K070490 - CirQlator ™**	**Proposed** **VPOD™ ITPR**
Biocompatibility	Externally communicating Tissue Prolonged duration of use (>24 hours, <30 days)	Externally communicating Tissue Prolonged duration of use (>24 hours, <30 days)

Table 3 – Description of the Differences

Features	**Predicate** **K070490 - CirQlator™**	**Proposed** **VPOD™ ITPR**
Vacuum source to create negative intrathoracic pressure	External vacuum source	Microprocessor controlled and monitored miniature blower
Design	Vacuum port for external vacuum	Does not require external vacuum source. Vacuum controlled by software from Graphic User Interface (GUI) with alarms and battery backed power supply.
Maximum level of negative pressure applied to airway	-9 mmHg (-12 cmH_2O) Fixed	-9 mmHg (-12 cmH_2O) Maximum and continuously variable as set by user from -2 to -12 cmH_2O.
Software driven	No	Yes
Operating conditions	0ºC to 40ºC 30% to 85% RH	10ºC to 35ºC 30% to 95% RH
Storage conditions	-20ºC to 60ºC 10% to 90% RH	-20ºC to 50ºC 10% to 90% RH

Substantial Equivalence Discussion

The VPOD ITPR is viewed as substantially equivalent to the predicate device because:

Indications –

- The VPOD ITPR is indicated for the temporary decrease in intrathoracic pressure to increase blood circulation and blood pressure, as prescribed by a physician, licensed practitioner, or qualified technician. Recommended duration of use is up to four hours.
- This is similar to the predicate – ACSI CirQlator™ - K070490.

Discussion -
There are no differences between the indications for use for the subject device and the predicate (K070490).

General Notes –
The VPOD™ Intrathoracic Pressure Regulator may benefit people needing assisted ventilation that suffer from states of poor circulation, low blood pressure, or insufficient cardiac preload that may be reflected by low blood pressure. The device is not intended for those patients who would not benefit from an increase in cardiac preload.

Routine monitoring (e.g., heart rate, blood pressure, oxygen saturation), and appropriate sedation that may include neuromuscular blockade, is required for use.

Patient Population –

- The patient population is those patient needing assisted ventilation that suffer from states of poor circulation, low blood pressure, or insufficient cardiac preload that may be reflected by low blood pressure.
- This is similar to the predicate – ACSI CirQlator™ - K070490.

Discussion -
There are no differences in the patient population for the subject device and the predicate (K070490).

Environment of Use –

- It is intended for pre-hospital (including EMS) and hospital use.

Discussion -
There are no differences in environment of use.

Technology –

- The principle of operation, namely applying a negative pressure to increase intrathoracic pressure is the same as the predicate.
- The subject device has its own means of generating a vacuum, the motor and blower, whereas the predicate must be connected to an external vacuum source.
    - As discussed above the difference of how vacuum is provided based upon our risk assessment and testing does not raise new concerns of safety or effectiveness.
- The ability to adjust the amount of negative pressure in the subject device vs. a fixed vacuum negative of the predicate allows the clinician more latitude in using the subject device on patients. Some patients may not tolerate the higher negative pressure initially and require a gradual increase to the maximum of -12 cmH_2O.

Discussion -
The differences as discuss below do not raise new concerns of safety and performance when compared to the predicate and tested.

Non-clinical Testing

Biocompatibility of Materials –

- The materials are considered Externally Communicating, Tissue, Limited durations (<24 hours) per ISO 10993-1
- Testing included
    - Cytotoxicity (ISO 10993-5)
    - Sensitization (ISO 10993-10)
    - Irritation (ISO 10993-10)
    - Acute Systemic Toxicity (ISO 10993-11)
    - Gas emission VOC with risk based assessment
    - Particulate Matter ($PM_{2.5}$)
- **Discussion -**
  The materials used in the subject device were tested and found to be non-cytotoxic, non-irritating, non-mutagenic, and with a margin of safety > 1.

Bench Performance
Device performance testing included:

Cleaning, Shelf-life, Effects of Aging	Validation and Verification of VPOD Motor Effects of aging
Electrical Safety, EMC	AAMI ANSI ES 60601-1 IEC 60601-1-2
Alarms	IEC 60601-1-8
Applicable requirements of ventilators	ISO 80601-2-12 Applicable requirements
Bench	Accuracy – airway pressure Flow rates Vacuum accuracy Simulated altitude Resistance to flow Compatibility with ventilator Pressure / flow Mechanical drop Dead space Leakage of blower Induced temperature rise / change
Batteries	UL 2054
Usability	

Comparative Performance
We have performed comparative performance testing; see the specific sections for full details. These tested included:

Animal Study
We performed an animal study comparing the subject device to the predicate. The results showed:

Improved Mean Arterial Pressure
Both the VPOD and the CirQlator improved mean arterial pressure by 17 mmHg (after bleed and recovery) at minute 30 of device use.

Maximum airway pressure
VPOD and CirQlator are initiated (turned on) after the 0 minute data is collected during inspiration by the ventilator throughout the study. The results showed no significant difference between the positive airway pressures of the CirQlator and the VPOD during device use.

Maximum negative airway pressure
There are no significant differences between the negative airway pressures achieved with either device demonstrating their substantial equivalence. Both devices achieved a negative expiratory airway pressure of approximately -9 mmHg (-12 cmH_2O).

Conclusion
Both devices are able to create equivalent negative airway pressures during the expiratory phase and improve circulation comparably when utilized in this model of compromised circulation.

These studies demonstrate the substantial equivalence of the VPOD to the CirQlator.

Discussion of Differences
The major differences between the proposed device and the predicate are:

The proposed device (VPOD) employs a miniature blower connected to the patient's airway (tracheal tube, etc.) and in series with the mechanical ventilator connection (WYE piece) which allows the patient to receive breaths through the blower. When the blower is not spinning and the VPOD is placed in the breathing circuit, it serves to freely pass breathing gas to-and-fro. When active, VPOD spins up to the user defined pressure setting and while still allowing the patient to receive breaths to-and-fro, it imparts a constant, regulated difference in pressure between the patient and the ventilator. The CirQlator is a mechanical device that relies upon regulated external vacuum (wall vacuum) in concert with a pressure driven valve to cycle between inspiration and exhalation. Inspiration/expiration cycling is driven by the positive pressure ventilation source. An integral regulator valve ensures that the maximum vacuum (-12 cmH_2O) is not exceeded.

VPOD allows exhaled gas to return through the mechanical ventilator's exhalation system. Sophisticated mechanical ventilators monitor and alarm based on measured exhaled volume from the patient. The VPOD does not perturb exhaled volume, or other ventilator monitors. The predicate CirQlator directs exhaled gas from the patient to wall suction, thereby causing the

mechanical ventilator low exhaled tidal and minute volume alarms to activate. Hence, the predicate requires that the mechanical ventilator's exhaled alarms be silenced or disabled during its use. Consequently, a clinician must constantly attend the patient during the use of the predicate to ensure that the patient is receiving adequate ventilation and that the breathing circuit connections are secure.

VPOD allows the user to adjust the vacuum level, whereas CirQlator was a fixed vacuum level of -12 cmH_2O expiratory airway pressure. In VPOD, the user can adjust the expiratory airway pressure in increments of -1 cmH_2O from -2 to -12 cmH_2O.

It is our view that the only significant difference that affects the safety or effectiveness of the intended device as compared to the predicate device is the integration of its microprocessor controlled vacuum source, patient and device monitors and alarms. The effect on intrathoracic pressure regulation is the same as CirQlator, but the proposed device does not perturb the performance of sophisticated mechanical ventilators and provides self-checking and monitoring features by virtue of the microprocessor based control system and graphic user interface.

Substantial Equivalence Conclusion

Based upon the performance testing and comparison to the legally marketed predicate device for indications for use, technology, and performance we believe we have demonstrated that the VPOD ITPR is substantially equivalent to the predicate device.