DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 10, 2017

Dear:

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,

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 below.

510(k) Number *(if known)*
K162968

Indications for Use *(Describe)*

This Device is to be used by properly trained personnel to deliver emergency, short term, constant flow, pressure cycled ventilator support on patients weighing 10kg and above.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

I. SUBMITTER

II. DEVICE

Name of Device: GAS OPERATED VENT™
Common or Usual Name: Ventilator, Emergency, Powered (Resuscitator)
Classification Name: Powered Emergency Ventilator
Regulation Number: 21 CFR 868.5925
Regulatory Class: II
Product Code: BTL
Classification Advisory Committee: Anesthesiology
Review Advisory Committee: Anesthesiology

III. PREDICATE DEVICE

K041473	Automatic Resuscitator (AR-Plus) *(Primary Predicate Device)*
K153733	Manometer *(Reference Device – For Material Compatibility Only)*

IV. DEVICE DESCRIPTION

The GAS OPERATED VENT™ provides short term, constant flow, pressure cycled ventilatory support in either pressure control or pressure support modes on patients weighing 10kg and above. In the pressure support mode, the rate dial of the GAS OPERATED VENT™ is set so that the baseline pressure is above the set PEEP allowing the patient to initiate inhalation by drawing the baseline pressure down to the set PEEP. The device includes the pulmonary modulator (an exhalation valve that opens at PIP and closes at PEEP) and a patient connector tee to supply gas flow, entrain additional air, and provides a redundant pop-off valve for patient care. The working mechanism of the GAS OPERATED VENT™ consists of a moving diaphragm which adds or subtracts spring force when it is moved from a horizontal to a vertical position, the addition or subtraction of spring force will affect the PIP setting by 1~3 cm-H_2O. The GAS OPERATED VENT™ will function in any position as long as the **final adjustments are made in a secured position** (strapped or taped to the patient).

The GAS OPERATED VENT™ is not an ICU stand alone ventilator with multiple monitoring features. Set up and use of the GAS OPERATED VENT™ is simple. Set desired flow and adjust pressure dial to obtain desired I-time and/ or tidal volume (see tidal volume chart in instructions), and adjust rate dial to obtain desired rate and I to E ratio.

Device Model Number:	6123-10
Device Accessories:	Elbow Flex Hose, Oxygen Tubing, Pressure Manometer
Interaction with Patient:	The Elbow Flex Hose has indirect contact with patient

V. INDICATIONS FOR USE

This device is intended to be use by properly trained personnel to deliver emergency, short term, constant flow, pressure cycled, ventilatory support on patients weighing 10kg and above.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Technical Modifications:

MR conditional – The new model of the Automatic Resuscitator has been modified with new springs made of Beryllium-Copper instead of the Stainless-Steel. This change was verified (in the Shellock MR Testing on Products Report) to make the device MR Conditional. The report concluded that the GAS OPERATED VENT™ can be used in an MRI environment with a static magnetic field of 3-Tesla or less, and a spatial gradient magnetic field of 10,000-gauss/cm or less. Shellock performs their tests based on ASTM F2052 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment. We have verified that the performance of the beryllium-copper springs is substantially equivalent to the stainless-steel springs.

New Entrainment Connectors for the 50% and 100% FiO_2 Delivery – The new device connectors include a combination knob that can be rotated from the 100% FiO_2 (a fully closed position of entrainment ports) to the 50% FiO_2 (a position of having entrainment ports open) versus the two connectors of the predicate device that the 100% FiO_2 connector should be completely removed to access the 50% FiO_2 connector. The modification facilitates the FiO2 change from 50% to 100% FiO_2 and vice versa. All testing data have shown and verified that the change in the knobs has not degraded the performance and the device delivers the required specifications.

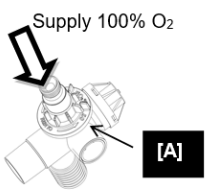
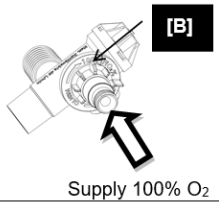
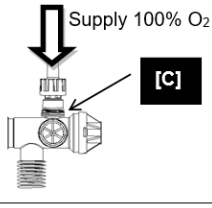
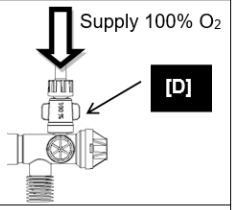
510(k) Summary / K162968 – GAS OPERATED VENT™

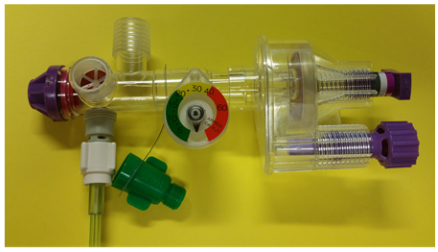
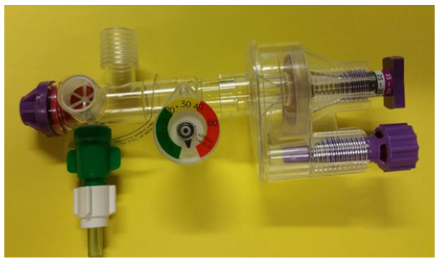
The tables below show the technological differences and similarities of our GAS OPERATED VENT™ compared to the predicate device (AR-Plus).

Operational Characteristics:

	NEW DEVICE	PREDICATE DEVICE
Device Name	VORTRAN® GO_2VENT™	VORTRAN® Automatic Resuscitator (VAR-Plus)
510(k) Number	N/A	K041473
Maximum Inspiratory Flow	40 L/min *Same as predicate device*	40 L/min
Ventilatory Frequency	Auto-adjusting to lung capacity [c] *Same as predicate device*	Auto-adjusting to lung capacity [c]
Peak Pressure Range	10 – 45 cm-H_2O [d] *Same as predicate device*	10 – 45 cm-H_2O [d]
PEEP	2 – 9 cm-H_2O [d] *Same as predicate device*	2 – 9 cm-H_2O [d]
Required Source Pressure	50 psig *Same as predicate device*	50 psig
Dead Space	4 ± 3 mL *Same as predicate device*	4 ± 3 mL
Inspiratory Resistance	3 ± 1 cm-H_2O / L / sec *Same as predicate device*	3 ± 1 cm-H_2O / L / sec
Expiratory Resistance	3 ± 1 cm-H_2O / L / sec *Same as predicate device*	3 ± 1 cm-H_2O / L / sec
High Pressure Pop-off	Yes, 60 cm H_2O *Same as predicate device*	Yes, 60 cm H_2O
Visual or Audible Indication of High Pressure	Yes *Same as predicate device*	Yes

Functional Characteristics:

	NEW DEVICE		PREDICATE DEVICE	
Device Name	VORTRAN® GO₂VENT™		VORTRAN® Automatic Resuscitator (VAR-Plus)	
510(k) Number	N/A		K041473	
FiO_2 Devliery	50% FiO_2 by entraining room air	FiO_2 of >85% when supplied with 100% O_2	50% FiO_2 by entraining room air	FiO_2 of >85% when supplied with 100% O_2
				
Method of Changing Delivery of FiO_2 when supplied with 100% O_2	[A] Delivers FiO_2 at 50% by entraining room air when setting the selector dial to the 50% mark on the new patient tee	[B] Delivers FiO_2 of >85% by NOT entraining room air when setting the selector dial to the 100% mark on the new patient tee	[C] Delivers FiO_2 at 50% by entraining room air when the 100% adaptor is removed, exposing the 50% entrainment nozzle on the patient tee	[D] Delivers FiO_2 of >85% by NOT entraining room air when the 100% adaptor is connected to the patient tee
Oxygen Concentration	Delivers FiO_2 >85% or 50% by entraining room air *Same as predicate device*		Delivers FiO_2 >85% or 50% by entraining room air [e]	

	NEW DEVICE	PREDICATE DEVICE
Device Name	VORTRAN® GO₂VENT™	VORTRAN® Automatic Resuscitator (VAR-Plus)
510(k) Number	N/A	K041473
50% FiO_2 by entraining room air		
FiO_2 of >85% when supplied with 100% O_2		

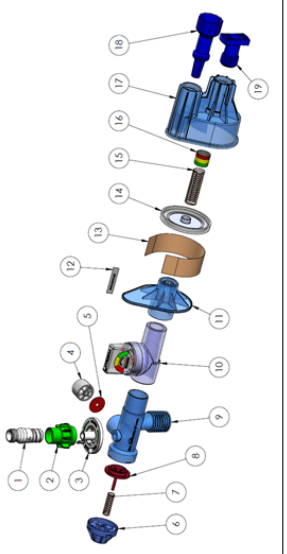
Material of Construction:

	NEW DEVICE	PREDICATE DEVICE	
Device Name	VORTRAN® GO$_2$VENT™	VORTRAN® Automatic Resuscitator (VAR-Plus)	VORTRAN® Manometer
510(k) Number	N/A	K041473	K153733
Date SE Decision	NA	July 15, 2004	September 16, 2016
Housing	K-Resin®, Polycarb *Same as predicate device*	K-Resin®	Polycarb
Internal Springs	Beryllium-Copper [f] *Same as predicate device*	302 Stainless Steel	Beryllium-Copper [f]
Pressure and Rate Dials	HDPE *Same as predicate device*	DOW® HDPE 12450 color blue	Acetal
One-Way Valve Body	HDPE *Same as predicate device*	DOW® HDPE 12450	N/A
Flapper Valve	Silicone *Same as predicate device*	Silicon Polymer	N/A
Diaphragm	Silicone *Same as predicate device*	Silicone	SILICONE/ Natural
Disk Center	Nylon *Same as predicate device*	Nylon	N/A

VII. PERFORMANCE DATA

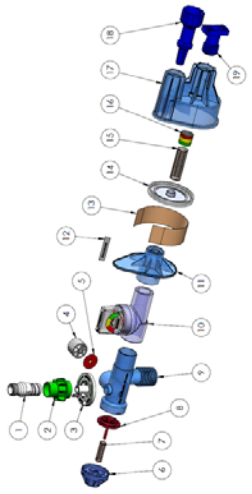
The following performance data were provided in support of the substantial equivalence determination.

- **Biocompatibility Testing**

Device Nature of Body Contact Category: **External Communicating**			Duration of Contact for the Device: **Up to 30 days**		
	Part No.	**Part Description**	**Patient Contact Status** / **Substantial Equivalence Device (510K #)**	**Material/Color**	
1.	6007	100% - 50% VAR Nozzle	**Indirect patient contact K153733**	Polycarbonate/White	
2.	6008	FiO2 Controller Knob	**Indirect patient contact K041473**	HDPE/Green	
3.	6009	Entrainment Barrel	**Indirect patient contact K153733**	Polycarbonate/White	
4.	2015	One-Way Valve Body	**Indirect patient contact K041473**	HDPE/Natural	
5.	2016	One-Way Valve Flapper	**Indirect patient contact K153733**	Silicone/Red	
6.	6005	Pop-Off Valve Cap	No patient contact	Polycarbonate/Blue	
7.	6010	Pop-Off Valve Spring	No patient contact	Beryllium Copper	
8.	2012	Pop-Off Valve Piston	**Indirect patient contact K041473**	HDPE/Red	
9.	6006	Patient Tee	**Indirect patient contact K041473**	K-Resin®/Clear/Blue	
10.	2291	Manometer Assembly	**Indirect patient contact K153733**	N/A	
11.	6003	Modulator Bottom, Single Port	**Indirect patient contact K153733**	Polycarbonate/Clear/ Blue	
14.	2182B	Diaphragm	No patient contact	Silicone/Natural	
	2181B	Hard Center	**Indirect patient contact K041473**	Nylon/Natural	

- **Biocompatibility Testing (Continued)**

Device Nature of Body Contact Category: **External Communicating**			Duration of Contact for the Device: **Up to 30 days**	
	Part No.	**Part Description**	**Patient Contact Status** **Substantial Equivalence Device (510K #)**	**Material/Color**
15.	6004	Pressure Dial Spring	No patient contact	Beryllium Copper
17.	6002	Modulator Top	No patient contact	Polycarbonate/Clear/ Blue
18.	6017	Rate Dial	No patient contact	HDPE/Blue
19.	6016	Pressure Dial	No patient contact	HDPE/Blue



Discussion:

1) **Rationale for Not Needing Biocompatibility Testing**: Considering the material used in the components of the new device (VORTRAN® GO_2VENT™) and the fact that the same material used as those in the predicated devices manufactured by VORTRAN Medical and produced with the same manufacturing process, the material of the new device is compatible and requires no additional biocompatibility testing.

- **Animal Study**

  None

- **Non-Clinical Performance Testing/Performance Data/Compliance with Performance Standards**

  The GAS OPERATED VENT™, just as the AR-Plus, meets the "Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans" ASTM Designation: F 920 – 93. A separate non-clinical test showed that all requirements were also met for ISO 10651-5, "Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators". The determination for substantial equivalence was based on a comparison of performance data between the new device and predicate device (FDA 510(k) No. K041473). The predicate device performance tests were documented. To demonstrate substantial equivalence, the new device was also tested using "ASTM F920-93 (Reapproved 1999)". In addition, the features that are considered technological differences were tested. The function of the new FiO_2 entrainment feature (at 50% and 100% FiO_2 settings) and device shelf-life were tested with the results documented. The new Beryllium-Copper springs were tested for performance and fatigue.

- **Clinical Studies**
  None

VII. CONCLUSIONS

- The GAS OPERATED VENT™ is substantially equivalent to a predicate device: The AR-Plus. The results from the nonclinical tests show that the device achieves predefined acceptance criteria for all assessments that were previously performed on the predicate device. GAS OPERATED VENT™, just as the AR-Plus, meets the "Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans" ASTM Designation: F 920 – 93. All requirements were also met for ISO 10651-5, “Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators”. The GAS OPERATED VENT™ has been shown to be substantially equivalent to the predicate device.