Vortran Medical Technology 1, Inc.
Adam Palumbo
Vice President of Engineering
21 Goldenland Court, Suite 100
Sacramento, California 95834

Re: K202219
Trade/Device Name: VORTRAN GO2VENT with PEEP Valve
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: Class II
Product Code: BTL
Dated: December 11, 2020
Received: January 12, 2021

Dear Adam Palumbo:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brandon Blakely, PhD
Acting Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K202219

Device Name
VORTRAN GO2VENT with PEEP Valve

Indications for Use *(Describe)*
The VORTRAN GO2VENT with PEEP Valve is to be used by properly trained personnel to deliver emergency, short-term, constant flow, pressure-cycled ventilatory support on patients weighing 10 kg 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.

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VORTRAN GO_2VENT with PEEP Valve
510(k) Summary /K202219

I. SUBMITTER

VORTRAN Medical Technology 1, Inc.
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Sacramento, CA 95834

Phone: 800-434-4034
Fax: 916-243-1338

Contact Person: Adam Palumbo
Contact Title: Vice President of Engineering
Date Prepared: May 31, 2020

II. DEVICE

Name of Device: VORTRAN GO_2VENT with PEEP Valve
Common or Usual Name: Powered emergency ventilator
Classification Name: Ventilator, Emergency, Powered (Resuscitator) (21 CFR 868.5925)
Regulatory Class: II
Product Code: BTL, BYE

III. PREDICATE DEVICE

VORTRAN GO_2VENT, K162968
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The device consists of a modulator (an exhalation valve that opens at PIP and closes at PEEP), a mechanical manometer, a resistor (which is referred to as the PEEP Valve) attached within the exhalation path for elevating the PEEP further than can be set with the modulator, a patient connector tee to supply gas flow, entrain additional air, and connect to a face mask or a tube inserted into a patient's airway, and two associated accessories. It is intended to be used by properly trained personnel in any environment in which emergency ventilation is required.

The VORTRAN GO_2VENT with PEEP Valve provides short-term, constant flow, pressure-cycled ventilatory support in either pressure control or pressure support mode. In pressure support mode, the rate dial of the VORTRAN GO_2VENT with PEEP Valve is set so that the baseline pressure is set above the set PEEP. This allows the patient to initiate inhalation by drawing the baseline pressure down to the set PEEP. In pressure control mode, the device will automatically cycle between PIP and PEEP when connected to a patient's airway.

The working mechanism of the VORTRAN GO_2VENT with PEEP Valve consists of a moving diaphragm that opens the exhalation path when the pressure reaches PIP and closes when the pressure reaches PEEP. Without the PEEP Valve, PEEP will be approximately 20% of the set PIP. With the PEEP Valve attached, the PEEP will be increased from this value up to 24 cm-H_2O depending on the patient's compliance and

the VORTRAN GO_2VENT with PEEP Valve's settings. The PEEP Valve is attached within the exhalation path by connecting it between the modulator and the patient connector tee. The pressure at which the diaphragm opens and closes against the valve is controlled by the amount of spring force acting against the diaphragm's movement. The spring force is adjusted by manually turning a threaded knob that varies the amount of spring compression.

The device is constructed of a variety of plastics such as K-Resin, HDPE, polycarbonate, and silicone, as well as copper beryllium springs. The VORTRAN GO_2VENT with PEEP Valve is an external communicating device with limited and prolonged tissue contact duration (up to 30 days) via the breathing gas pathway.

The associated accessories were included with the cleared predicate device (K162968) and include:

- Elbow flex hose for connecting the patient connector tee to a face mask or a tube inserted into a patient's airway
- Oxygen tubing for connecting the patient connector tee to a gas supply

V. INDICATIONS FOR USE

The VORTRAN GO_2VENT with PEEP Valve is to be used by properly trained personnel to deliver emergency, short-term, constant flow, pressure-cycled ventilatory support on patients weighing 10 kg and above.

The Indications for Use statement for the VORTRAN GO_2VENT with PEEP Valve is identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Pulmonary modulation is the technological principle for both the subject and predicate devices. It is based on the use of an exhalation valve that opens at peak inspiratory pressure (PIP) and closes at positive end-expiratory pressure (PEEP), which allows the device to provide automatic ventilatory support. Aside from the addition of one extra component (that consists of one piece) that makes up the PEEP Valve, the subject and predicate devices are identical, including the following technological elements:

- Modulator – contains the exhalation valve that opens at PIP and closes at PEEP
- Exhalation valve – consists of a diaphragm and a spring that adds or subtracts force to control when the diaphragm opens and closes the valve
- Springs – all springs consist of copper beryllium in order to keep the entire device non-conducting, non-ferrous, non-magnetic, and non-metallic
- Manual controls – exhalation time and PIP are controlled by turning two knobs that adjust exhalation flow resistance and spring force, respectively
- Patient connector tee – to supply gas flow, entrain additional air, and
- Pop-off valve – used as a safety mechanism for preventing pressures in excess of 60 cm-H_2O
- Manometer – a mechanical pressure indicator to monitor the PIP and PEEP

The following technological differences exist between the subject and predicate devices:

- The subject device includes a positive end-expiratory pressure breathing attachment in order to further raise the pressure in which the device's exhalation valve will close.

VII. PERFORMANCE DATA

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

Biocompatibility testing
The biocompatibility evaluation for the VORTRAN GO_2VENT with PEEP Valve was conducted in accordance with Guidance for Industry and Food and Drug Administration Staff "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,'" June 16, 2016, as well as the following International Organization for Standardization documents recognized by the FDA: ISO 10993-1:2018 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" and ISO 18562-1:2017 "Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process." As a result of the evaluation to these standards, it was determined that biocompatibility testing was not needed.

The VORTRAN GO_2VENT with PEEP Valve is an external communicating device with limited and prolonged tissue contact duration (up to 30 days) via the breathing gas pathway.

Mechanical testing
Performance testing was conducted on the VORTRAN GO_2VENT with PEEP Valve to determine its specifications regarding ventilatory parameters. The subject device complies with ISO 10651-5:2006 "Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators."

Connection ports on the VORTRAN GO_2VENT with PEEP Valve were designed to ISO 5356-1:2015 "Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets."

Animal and clinical studies
There were no animal or clinical studies done for the subject device.

VIII. CONCLUSIONS

The non-clinical data support the safety of the VORTRAN GO_2VENT with PEEP Valve, demonstrate that the subject device should perform as intended in the specified use conditions, and demonstrate that the subject device performs comparably to the predicate device that is currently marketed for identical indications for use. The data demonstrate that the VORTRAN GO_2VENT with PEEP Valve is substantially equivalent to its predicate device.