September 18, 2019

VORTRAN Medical Technology 1, Inc.
James Lee
Executive VP & COO
21 Goldenland Court, Suite 100
Sacramento, California 95834

Re: K182292
Trade/Device Name: VORTRAN APM-Plus
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway Pressure Monitor
Regulatory Class: Class II
Product Code: CAP
Dated: August 30, 2019
Received: September 16, 2019

Dear James Lee:

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,

James Lee
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)*
K182292

Device Name
VORTRAN® APM-Plus

Indications for Use *(Describe)*
The VORTRAN® APM-Plus is a multiple-patient-use device intended to monitor a positive-pressure device that connects to an adult or pediatric patient ≥ 10 kg. The device alarms when the conditions (pressure and/or rate, as applicable) are outside of the user selected high and low alarm limits. In PAP Mode, it displays only real-time breathing circuit pressure; in Resuscitator Mode, it displays ventilation parameters in addition to the pressure information. It may be used with positive pressure devices which do not include pressure measurement capabilities, e.g. resuscitation bags, automatic resuscitators, and CPAP, or as an independent backup pressure monitor for devices with pressure measurement capability. The device is designed to be portable and can be used in stationary or portable situations in hospitals and sub-acute institutions. For professional use only.

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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"510(k) Summary" as per 807.92(c)
VORTRAN® APM-Plus

I. SUBMITTER

VORTRAN® Medical Technology 1, Inc.
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Sacramento, CA 95834 USA

Phone: (800) 434-4034
Fax: (916) 648-9751

Contact Person: James Lee
Contact Title: Executive Vice President & COO
Date Prepared: August 17, 2018

II. DEVICE

Name of Device: VORTRAN® APM-Plus
Common or Usual Name: Airway Pressure Monitor
Classification Name: Monitor, Airway Pressure (Includes Gauge And /or Alarm)
Regulation Number: 21 CFR 868.2600
Regulatory Class: II
Product Code: CAP
Classification Advisory Committee: Anesthesiology

III. PREDICATE DEVICE

K992101	Criterion 40 Airway Pressure Monitor (Primary)
K103639	VORTRAN® Airway Pressure Monitor (Reference)

IV. DEVICE DESCRIPTION/PRINCIPLE OF OPERATION

The VORTRAN® APM-Plus is a battery (2 x AA) operated, microprocessor controlled, portable, self-contained device designed for monitoring a positive airway-pressure device such as a resuscitator or CPAP. The VORTRAN® APM-Plus is housed in a plastic enclosure. It connects to the positive-pressure device under monitor via pneumatic pressure tubing and receives the pressure signals using its solid-state pressure transducer. The pressure signals are used to calculate the related characteristics which are displayed on the LCD screen. The values are used to trigger alarms that alert the user of any abnormal pressure conditions. The software algorithm constantly monitors the data and if/when the pressure

characteristics are outside of the user-set limits, an alarm will be activated. The alarms are both visual and audible. For ease of use, the VORTRAN® APM-Pus software provides two modes of operations: Resuscitator Mode and PAP Mode. When the device is turned on, the user can select one of the two modes. In each mode, the pressure data shown is suitable for the device under monitoring:

- **Monitoring/Alarms, Resuscitator Mode**: The VORTRAN® APM-Plus will display PIP, PEEP, Respiratory Rate, Inspiratory and Expiratory Time, and I:E Ratio. When a connected pressure-cycled device stops cycling for a user-set time or the pressure falls under the user-set limit, the VORTRAN® APM-Plus will activate the NON-CYCLING ALARM or LOW PEEP ALARM, respectively. In addition, when respiratory rate or the pressure exceeds their user-set limits, the HIGH RATE or HIGH PIP alarm will activate, respectively.

- **Monitoring/Alarms, PAP Mode**: The VORTRAN® APM-Plus will display real-time pressure. When a connected constant-pressure device falls outside of the user-set range, the HIGH PRESSURE or LOW PRESSURE ALARM will activate.

The VORTRAN® APM-Plus has a flashing red LED and an audible sound, while simultaneously displaying the alarm condition on the LCD.

The accessories were all cleared with the reference device's 510(k) submission K103639 (VORTRAN® Airway Pressure Monitor) and include:

- Pressure tubing for connecting the VORTRAN® APM-Plus to a breathing circuit
- A hydrophobic filter for protecting the device from any condensate that may pass through the breathing circuit
- A luer connector for connecting the pressure tubing to the hydrophobic filter
- A tee adapter for connecting the pressure tubing in-line with a breathing circuit that does not have its own outlet

V. INTENDED USE

The VORTRAN® APM-Plus is used to measure airway pressure for patients utilizing positive pressure devices where monitoring is desired.

VI. INDICATIONS FOR USE

The VORTRAN® APM-Plus is a multiple-patient-use device intended to monitor a positive-pressure device that connects to an adult or pediatric patient ≥ 10 kg. The device alarms when the conditions (pressure and/or rate, as applicable) are outside of the user selected high and low alarm limits. In PAP Mode, it displays only real-time breathing circuit pressure; in Resuscitator Mode, it displays ventilation parameters in addition to the pressure information. It may be used with positive pressure devices which do not include pressure measurement capabilities, e.g. resuscitation bags, automatic resuscitators, and CPAP, or as an independent backup pressure monitor for devices with pressure measurement capability. The device is designed to be portable and can be used in stationary or portable situations in hospitals and sub-acute institutions. For professional use only.

VII. DIFFERENCES IN INDICATIONS FOR USE TO THE PRIMARY PREDICATE DEVICE

The VORTRAN® APM-Plus and its primary predicate device have the following differences in their Indications for Use:

- The Criterion 40 Airway Pressure Monitor displays real-time pressure as well as peak pressure. The VORTRAN® APM-Plus, when in PAP Mode, only displays the real-time pressure.

- In Resuscitator Mode, the VORTRAN® APM-Plus displays Peak Inspiratory Pressure (PIP), Positive End-Expiratory Pressure (PEEP), Breath Rate, Inspiratory Time (I-Time), Expiratory Time (E-Time), and the ratio of Inspiratory Time to Expiratory Time (I:E Ratio), while the Criterion 40 only displays real-time pressure and peak pressure. These technological differences do not raise different questions of safety and effectiveness, as evidence by the substantial equivalence comparison to the reference predicate device, the VORTRAN® Airway Pressure Monitor, which has all the aforementioned parameters.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following tables provide a comparison between device characteristics:

General Characteristics:

	NEW DEVICE	PRIMARY	REFERENCE
Device Name	VORTRAN® APM-Plus	Criterion 40 Airway Pressure Monitor	VORTRAN® Airway Pressure Monitor
Patient Population	Adult or pediatric patients (10 kg and above) utilizing positive pressure devices	Any patient utilizing positive pressure devices and the clinician desires to have pressure monitoring.	Adults 40 kg and above (Model 3900) and Pediatrics 10 kg and above (Model 3800)
Patient Interface/Method of Deployment	Connected via pneumatic tubing (of the connection kit) to a tee fitting or Luer outlet within the breathing circuit of a resuscitator, CPAP, or other positive pressure device.	Airway adapter placed in the circuit or connection to a face mask	Connects to any breathing circuit that is connected to a patient.
Environment of Care	Hospitals and sub-acute institutions; designed to be used in stationary or portable situations	Hospitals, sub-acute institutions, home care settings; stationary and intra-institution transport only.	To be used by properly trained personnel in an environment in which the clinician desires to have pressure monitoring.
Sterility	Non-sterile (device and accessories)	Non-sterile	Non-sterile
Type of Use	Prescription Use (21CFR801 Subpart D)	Not specified	Prescription Use (21CFR801 Subpart D)

Physical Characteristics:

	NEW DEVICE	PRIMARY	REFERENCE
Device Name	VORTRAN® APM-Plus	Criterion 40 Airway Pressure Monitor	VORTRAN® Airway Pressure Monitor
Size	110 mm x 64 mm 33 mm (4.3 in x 2.5 in x 1.3 in)	198 mm x 94 mm x 188 mm (7.9 in x 3.7 in x 7.4 in)	81 mm x 56 mm x 48 mm (3.2 in x 2.2 in x 1.9 in)
Weight	150 g (with 2 AA batteries)	680 g	125 g (with 9V battery)
Enclosure Construction	ABS Plastic	Unspecified Plastic	ABS Plastic

"510(k) Summary" as per 807.92(c)
VORTRAN® APM-Plus

Technological/Principles of Operation Characteristics:

	NEW DEVICE	PRIMARY	REFERENCE
Device Name	VORTRAN® APM-Plus	Criterion 40 Airway Pressure Monitor	VORTRAN® Airway Pressure Monitor
Method of Connection	Female Luer connection	Female Luer connection	Female Luer connection
Alarms	YES	YES	YES
Measurement Device	Solid state pressure sensor	Solid state pressure sensor	Solid state pressure sensor
Output	Digital readout of pressures	Digital readout of pressures	Digital readout of pressures
Control Method	Internal microprocessor	Internal microprocessor	Internal microprocessor
Power Type	DC input (2 x AA alkaline batteries)	AC Mains input (and DC input backup battery)	DC input (1 x 9V alkaline battery)

Performance Specifications:

	NEW DEVICE	PRIMARY	REFERENCE
Device Name	VORTRAN® APM-Plus	Criterion 40 Airway Pressure Monitor	VORTRAN® Airway Pressure Monitor
Connected Devices	Positive pressure devices (including pressure-cycled devices)	Positive pressure devices (e.g. bubble CPAP, resuscitators)	Pressure-cycled devices (e.g. resuscitators)
Displayed Measurements	Resuscitator Mode: PIP, PEEP, Respiratory Rate, Inspiratory Time, Expiratory Time, Inspiratory: Expiratory Ratio PAP Mode: Real-time Pressure	Real-time Pressure, Peak Pressure	PIP, PEEP, Respiratory Rate, Inspiratory Time, Expiratory Time, Inspiratory: Expiratory Ratio

"510(k) Summary" as per 807.92(c)
VORTRAN® APM-Plus

Performance Specifications, continued:

	NEW DEVICE	PRIMARY	REFERENCE
Device Name	VORTRAN® APM-Plus	Criterion 40 Airway Pressure Monitor	VORTRAN® Airway Pressure Monitor
Pressure Display Range	0 to 55 cm-H_2O	0 to 99.5 cm-H_2O	0 to 50 cm-H_2O
Pressure Display Accuracy	± 1 cm-H_2O	± (1 cm-H_2O + 3% of reading) rounded up to nearest 0.5 cm-H_2O	± 10% of reading
Pressure Display Resolution	Resuscitator Mode: 1 cm-H_2O PAP Mode: 0.1 cm-H_2O	0.5 cm-H_2O	1 cm-H_2O
Respiratory Rate Display Range	0 to 99 BPM	N/A	0 to 55 BPM
Respiratory Display Rate Accuracy	± 10%	N/A	± 10%
Respiratory Rate Display Resolution	1 Breath per Minute	N/A	1 Breath per Minute
I-Time & E-Time Display Range	0 to 9.9 seconds	N/A	0 to 9.9 seconds
I-Time & E-Time Display Accuracy	± 10%	N/A	± 10%
I-Time & E-Time Display Resolution	0.1 second	N/A	0.1 second
I:E Ratio Display Range	1:0.0 to 1:9.9	N/A	1:0.0 to 1:9.9
I:E Ratio Display Accuracy	± 10%	N/A	± 10%

"510(k) Summary" as per 807.92(c)

VORTRAN® APM-Plus

Performance Specifications, continued:

	NEW DEVICE	PRIMARY	REFERENCE
Device Name	VORTRAN® APM-Plus	Criterion 40 Airway Pressure Monitor	VORTRAN® Airway Pressure Monitor
I:E Ratio Display Resolution	0.1	N/A	0.1
Alarm Delay	Yes, Non-Cycling Alarm Only: 1–20 s	Yes: 1-20 s	Yes, Non-Cycling Alarm Only – 15 s for Adult Model 3900, 8 s for Pediatric Model 3800
High Pressure Alarm Range and Resolution	1 to 50 cm-H_2O, Resolution of 1 cm-H_2O	5 to 99 cm-H_2O, Resolution of 1 cm-H_2O	Fixed at 50 cm-H_2O for Adult Model 3900, Fixed at 35 cm-H_2O for Pediatric Model 3800
Low Pressure Alarm Range and Resolution	1 to 15 cm-H_2O, Resolution of 1 cm-H_2O	1 to 20 cm-H_2O, Resolution of 1 cm-H_2O	N/A
High Rate Alarm Range and Resolution	12 to 99 BPM, Resolution of 1 BPM	N/A	Fixed at 50 BPM for Adult Model 3900, Fixed at 55 BPM for Pediatric Model
Non-Cycling Alarm Range and Resolution	1 to 20 seconds, Resolution of 1 second	N/A	Fixed at 15 seconds for Adult Model 3900, Fixed at 8 seconds for Pediatric Model 3800
Low Battery Alarm	YES	YES (when using internal backup battery)	YES
Battery Life	164 Hours (Worst-Case)	Unknown	27 Hours (Worst-Case)
Calibration	None	Unknown	None

IX. PERFORMANCE DATA

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

- **Biocompatibility Testing**
  The patient contacting materials, considered to be in the patient's gas flow pathway, include the accessory kit (pressure tubing, hydrophobic filter, luer connector, and tee adapter) and solid-state pressure transducer. The materials in said components of the VORTRAN® APM-Plus, in their final finished form are identical to the accessory kit and solid-state pressure transducer of the cleared reference device in K103639, the VORTRAN® Airway Pressure Monitor, in formulation, processing, and sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

- **Electrical Safety and Electromagnetic Compatibility (EMC)**
  The VORTRAN® APM-Plus was evaluated as medical electrical equipment, under the classification of "Internally Powered Device" and was found to be compliant with the following IEC standards (and applicable IEC collateral standards, as required by ISO 80601-2-55):

  - Electrical safety testing per IEC 60601-1
  - Electromagnetic compatibility testing per IEC 60601-1-2
  - Usability Study as per IEC 60601-1-6
  - Alarms designed as per IEC 60601-1-8
  - Software Development Process as per IEC 62304

- **Software Verification and Validation Testing**
  The embedded software was developed in accordance with FDA guidelines for a MODERATE Level of Concern. Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software lifecycle process was assessed to be in accordance with IEC 62304.

- **Risk Management**
  Risk Management and FMEA was assessed to (and found to be in compliance with) ISO 14971.

- **Shelf Life**
  An accelerated shelf life test was performed and met the acceptance criteria for a simulated age of 1 year.

- **Clinical Studies**
  None

X. CONCLUSION

The VORTRAN® APM-Plus's capabilities have been tested and compared to the predicate devices and the results support the substantial equivalence of the VORTRAN® APM-Plus.