DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

September 16, 2016

VORTRAN Medical Technology 1, Inc.
Mr. James Lee
Executive Vice President & COO
21 Goldenland Court, #100
Sacramento, California 95834

Re: K153733
Trade/Device Name: VORTRAN Manometer
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway Pressure Monitor
Regulatory Class: II
Product Code: CAP
Dated: August 9, 2016
Received: August 17, 2016

Dear Mr. 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. 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 yours,

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)*
Unknown K153733

Device Name

VORTRAN Manometer

Indications for Use *(Describe)*

The VORTRAN Manometer is a single patient use device intended to provide visual indication of a patient's airway pressure during ventilation from 0 to 60 cm-H2O. It may be attached to the manometer port on ventilation devices such as resuscitators, resuscitation bags, hyperinflation bags, CPAP Masks or CPAP Circuits.

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 Medical Technology 1, Inc.

August 9, 2016

510(k) Summary / K153733 - VORTRAN® Manometer

I. SUBMITTER

VORTRAN Medical Technology 1, Inc.
21 Goldenland Court, Suite 100
Sacramento, CA 95834 USA

Phone: (800) 434-4034
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Contact Person: James Lee
Date Prepared: August 9, 2016

II. DEVICE

Name of Device: VORTRAN® Manometer
510(k) Number: K153733
Regulation Description: Airway Pressure Monitor
Device: Monitor, Airway Pressure (Includes Gauge And/Or Alarm)
Regulation Number: 21 CFR 868.2600
Regulatory Class: II
Product Code: CAP
Classification Advisory Committee: Anesthesiology
Review Advisory Committee: Anesthesiology

III. PREDICATE DEVICE

K954486	Mercury Medical® Disposable Airway Pressure Manometer
K040991	Ambu® Disposable Pressure Manometer
K003497	DPM™ – Disposable Pressure Monitor
K041473	VORTRAN Automatic Resuscitator (VAR-Plus) (*For Material Compatibility Only*)
K003684	Percussiveneb (*For Material Compatibility Only*)
K920443	MiniNEB and VISAN-Neonatal (*For Material Compatibility Only*)

IV. DEVICE DESCRIPTION

The VORTRAN Pressure Manometer provides pressure readings from a breathing circuit in the range of 0 to 60 cm-H_2O. The pressure readouts are approximate with an accuracy of ±2 cm-H_2O for a low pressure range from 0 to 20 cm-H_2O; ±3 cm-H_2O for a pressure range of 20 to 40 cm-H_2O; and ±5 cm-H_2O for pressures above 40 cm-H_2O. The manometer design requirements include: the pressure range of 0 to 60 cm-H_2O, connection to a breathing circuit via a 22 mm male-female adaptor, and having a life expectancy as a single patient multiple use device. It accommodates connections through the option of a 22 mm tee or 15 mm port. The manometer includes a translucent enclosure that allows the pressure indicator needle to be seen from all sides.

The manometer label has three color zones of green, yellow, and red to give enhanced visual support during ventilation. The color coded scale indicates the following: green is 0 to 20 cm-H_2O; yellow is 20 to 40 cm-H_2O, and red is for pressures above 40 cm-H_2O. The color coded scale is only for visual support and the correct ventilation pressure must be determined by the medical professional.

V. INDICATIONS FOR USE

The VORTRAN Manometer is a single patient use device intended to provide visual indication of a patient's airway pressure during ventilation from 0 to 60 cm-H_2O. It may be attached to the manometer port on ventilation devices such as resuscitators, resuscitation bags, hyperinflation bags, CPAP Masks or CPAP Circuits.

DISCUSSION:

- The intended use of the new device and the predicate devices are to measure the airway pressure in the range of 0 to 60 cm –H_2O.
- The difference in the verbiage of how the manometers are connected to a ventilation device is informational only and will not affect the safety and effectiveness of the manometer.
- The device labeled as "single patient use" and the predicate labeled as "disposable" product have the same intended use and will not affect the safety and effectiveness.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below shows the technological differences and similarities of our manometer compared to the predicate devices.

	NEW DEVICE		PREDICATE DEVICE		
Device Name	VORTRAN® Manometer / Tee Connection	VORTRAN® Manometer / Vertical Connection	Mercury Medical® Disposable Airway Pressure Manometer	Ambu® Disposable Pressure Manometer	DPM™ – Disposable Pressure Monitor
Technology / Mechanisms *Similar* or *Different*					
Pressure Barrier	• Diaphragm		• Diaphragm ***Similar***	• Diaphragm ***Similar***	• Sealed O-ring Slider ***Different***
Counter Force	• Spring		• Spring ***Similar***	• Spring ***Similar***	• Spring ***Similar***
Method of translating in-line air pressure	• Displacement of diaphragm against spring (counter force)		• Displacement of diaphragm against spring (counter force) ***Similar***	• Displacement of diaphragm against spring (counter force) ***Similar***	• Displacement of sealed O-ring slider moving upwared ***Different***
Indicator Mechanism	• Rack and Pinion Gear		• Screw (Spiral Gear) ***Different***	• Extending Diaphragm ***Different***	• Displacing O-ring Slider ***Different***
Indicator Movement	• Rotational – force pushes the rack, resulting in rotation of pinion gear/indicator		• Rotational – force pushes threaded screw component, rotating the indicator ***Similar***	• Linear – force pushes the center of diaphragm, which extends upwards until it lines up with pressure indication labels ***Different***	• Linear – force pushes the slider upwards until it lines up with pressure indication labels ***Different***
Pressure Limits	• 0 ~ 60 cm H_2O		• 0 ~ 60 cm H_2O ***Similar***	• 0 ~ 60 cm H_2O ***Similar***	• 0 ~ 60 cm H_2O ***Similar***

	NEW DEVICE		PREDICATE DEVICE		
Device Name	VORTRAN® Manometer / Tee Connection	VORTRAN® Manometer / Vertical Connection	Mercury Medical® Disposable Airway Pressure Manometer	Ambu® Disposable Pressure Manometer	DPM™ – Disposable Pressure Monitor
Display Increments	• 10, 20, 30, 40 and 60 cm H_2O		• 5, 10, 15, 20, 30, 40 and 60 cm H_2O	• 5, 10, 15, 20, 30, 40 and 60 cm H_2O	• 0, 10, 20, 30, 40, 50 and 60 cm H_2O
Color Coded	Color coded: • Green 0 ~ 20 cm H_2O • Yellow 20 ~ 40 cm H_2O • Red 40 ~ 60 cm H_2O		Color coded: • Green 0 ~ 20 cm H_2O • Yellow 20 ~ 40 cm H_2O • Red 40 ~ 60 cm H_2O	Color coded: • Green 0 ~ 20 cm H_2O • Yellow 20 ~ 40 cm H_2O • Red 40 ~ 60 cm H_2O	Not color coded
Color Coded Feature					Not color coded
Operating & Storage Temp	Not Recorded		Not Recorded	Operating: - 18°C to 50°C Storage: - 40°C to 60°C	Not Recorded

- **Biocompatibility Testing**
  The VORTRAN Manometer has four components that have indirect patient contact that use the same material as the predicate devices manufactured by VORTRAN Medical. The following table lists the component name, their material, cleared device name, and 510k Number/Date.

Component Name	Material	Cleared Device Name	501k Number / Date
Tee Connector & Vertical Connector	Polycarbonate / Clear Blue	VORTRAN MiniNEB (a.k.a. MiniHEART Nebulizer)	K920443 / July 02, 1992
Diaphragm Support Disk	Polycarbonate / Clear Blue	VORTRAN MiniNEB (a.k.a. MiniHEART Nebulizer)	K920443 / July 02, 1992
Rack	Acetal	VORTRAN Device, Positive Pressure, Breathing	K003684 / February 23, 2001
Diaphragm	Silicon	VORTRAN Ventilator, emergency, powered	K041473 / July 15, 2004

VII. PERFORMANCE DATA

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

- **Animal Study**

  None

- **Clinical Studies**

  None

- **Performance Data**
  The VORTRAN Manometer will indicate airway pressure with an indicator needle that shows PIP (Peak Inspiratory Pressure) and PEEP (Positive End Expiratory Pressure) in cm-H_2O. The indicator needle is associated with a linear rack and pinion gear tied to a moveable diaphragm. Changes in airway pressure are measured via the moveable diaphragm and with the indicator needle that will rotate approximately 180° to indicate pressure range from 0 to 60 cm- H_2O

- **Clinical Application**
  The VORTRAN Manometer is connected to the patient via a "Tee" 15 mm/22 mm ID/OD or "Vertical" plastics connector.

- **Compliance with Performance Standards**
  ISO 5356-1 Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets

VIII. CONCLUSIONS

Based on the performance comparison of bench testing, the VORTRAN Manometer will perform as intended in the specified use conditions. The equivalent (SE) comparison data demonstrate that the VORTRAN Manometer device performs substantially equivalent to the predicate device that is currently marketed for the same intended use.