May 25, 2018

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

Re: K173914
Trade/Device Name: VORTRAN Cuff Inflator (VCI)
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: April 13, 2018
Received: April 18, 2018

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. 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,

Michael J. Ryan -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173914

Device Name

VORTRAN® Cuff Inflator (VCI)

Indications for Use *(Describe)*

The VORTRAN® Cuff Inflator (VCI) is intended to measure and regulate the intra-cuff pressure of Endotracheal tubes, Tracheostomy tubes and Laryngeal Mask Airways (LMAs). The VORTRAN® Cuff Inflator (VCI) is used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities, and outpatient clinics, where a patient may be intubated.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

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

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

Contact Person: James Lee
Date Prepared: May 25, 2018

II. DEVICE

Name of Device: VORTRAN® Cuff Inflator (VCI)
Common or Usual Name: Endotracheal cuff pressure regulator
Classification Name: Cuff, Tracheal Tube, Inflatable
Regulation Number: 21 CFR 868.5750
Regulatory Class: II
Product Code: BSK
Classification Advisory Committee: Anesthesiology
Review Advisory Committee: Anesthesiology

III. PREDICATE AND REFERENCE DEVICE

K912723	Posey Cufflator (Predicate Device)
K122721	Hospitech AG Cuffill (Reference Device)
K142103	Teleflex Medical CUFF PILOT, SURE SEAL (Reference Device)
K153733	VORTRAN® Manometer *(*Reference Device - *For Material Compatibility Only)*
K041473	VORTRAN® Automatic Resuscitator (VAR-Plus) *(*Reference Device - *For Material Compatibility Only)*

IV. DEVICE DESCRIPTION

The VORTRAN® Cuff Inflator (VCI) is a disposable, hand-held measuring device intended to measure and manually regulate intra-cuff pressure of Endotracheal, Tracheostomy, and LMA tubes.

V. INDICATIONS FOR USE

The VORTRAN® Cuff Inflator (VCI) is intended to measure and regulate the intra-cuff pressure of Endotracheal tubes, Tracheostomy tubes and Laryngeal Mask Airways (LMAs). The VORTRAN® Cuff Inflator (VCI) is used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities, and outpatient clinics, where a patient may be intubated.

VI. INTENDED POPULATION

Intubated patients

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The tables below show the technological differences and similarities of our VORTRAN® Cuff Inflator (VCI) compared to the predicate devices.

Operational Characteristics:

	NEW DEVICE	PREDICATE DEVICE	REFERENCE DEVICE
Device Name	VORTRAN® Cuff Inflator (VCI)	Posey Cufflator	Hospitech AG Cuffill
510(k) Number	K173914/S002	K912723	K122721
Technology	Inflation – Bellows pump Measurement – Mechanical gauge *Same as predicate device*	Inflation – Bellows pump Measurement – Mechanical gauge	Inflation – Syringe plunger Measurement – Electronic Pressure Sensor
Method of Inflating Cuff	Manually press bellows pump *Same as predicate device*	Manually press bellows pump	Manually press syringe plunger
Method of Deflating Cuff	Manually press air vent button *Same as predicate device*	Manually press air vent button	Manually pull out syringe plunger
Attaches to Cuff Inflation Pilot	Via male Luer fitting *Same as predicate devices*	Via male Luer fitting	Via male Luer fitting
Types of airways to which it can be used	Endotracheal tubes, tracheostomy tubes, and Laryngeal Mask Airways (LMAs) *Same as predicate devices*	Endotracheal tubes or tracheal tubes	Endotracheal tubes, tracheotomy tubes, and Laryngeal Mask Airways (LMAs)

Pressure Accuracy and Range:

	NEW DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
Device Name	VORTRAN® Cuff Inflator (VCI)	Posey Cufflator	Hospitech AG Cuffill	SureSeal™ with Cuff Pilot™
510(k) Number	K173914/S002	K912723	K122721	K142103
Pressure Range of Device (1)	0-60 cm-H_2O	0-120 cm-H_2O	0-99 cm-H_2O	0-80 cm-H_2O
Accuracy of Cuff Pressure Measurement (1)	± 3 cm-H_2O within the typical operating range of 20 – 40 cm-H_2O	± 2 cm-H_2O	± 2 cm-H_2O	± 5 cm-H_2O

(1) *A typical range for intra-cuff pressure is 25-34 cm-H_2O. The operation of the VORTRAN® Cuff Inflator (VCI) within this range has no significant difference, in comparison to its predicate or reference devices, and does not raise different questions of safety and effectiveness.*

Physical Characteristics:

	NEW DEVICE	PREDICATE DEVICE	REFERENCE DEVICE
Device Name	VORTRAN® Cuff Inflator (VCI)	Posey Cufflator	Hospitech AG Cuffill
510(k) Number	K173914/S002	K912723	K122721
Size	3 in. x 2 in. x 1.8 in.	None specified	Length: 7.87 in. Diameter (ID): 0.59 in.
Weight	30 grams	None specified	18 grams

Material of Construction:

The VORTRAN® Cuff Inflator (VCI) uses the same materials as predicate devices manufactured by VORTRAN Medical. The following table lists the component name, their material, cleared device name, and 510k Number/Date.

	NEW DEVICE	REFERENCE DEVICE FOR MATERIAL ONLY	REFERENCE DEVICE FOR MATERIAL ONLY
Device Name	VORTRAN® Cuff Inflator (VCI)	VORTRAN® Manometer	VORTRAN® Automatic Resuscitator (VAR-Plus)
510(k) Number	**K173914/S002**	K153733	K041473
Date SE Decision	N/A	September 16, 2016	July 15, 2004
All Plastic Components: Body, Pump Enclosure, Pump Seal Disk, Pump Spring Cap, Pump Lock Ring, Release Enclosure, Release Seal Disc, Release Spring Cap	**Polycarb** *Same as reference device (VORTRAN® Manometer)*	Manometer Top, Gear End Plate, Tee Connector, Diaphragm Support Disk, and Vertical Connection: **Polycarb**	N/A
All Rubber Components: Pump, Quad Rings	**Silicone** *Same as reference devices*	Diaphragm: **Silicone**	Diaphragm: **Silicone**
All Springs: Pump Spring, Release Spring	**Stainless Steel** *Same as reference device (VORTRAN® Automatic Resuscitator VAR-Plus)*	N/A	Internal Springs: **Stainless Steel**
Manometer Assembly:	*Entire assembly identical to reference device (VORTRAN® Manometer)*	All materials and components cleared under 510(k) No. K153733	N/A

VIII. PERFORMANCE DATA

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

- **Biocompatibility Testing**
  Neither the VORTRAN® Cuff Inflator (VCI), nor the air pumped from it, comes in direct or indirect contact with the patient or the user. Therefore, as per ISO 10993-1, there is no requirement for the VORTRAN® Cuff Inflator (VCI) components or its materials to be tested for biocompatibility.

- **Animal Study**

  N/A
- **Clinical Studies**
  None

- **Non-Clinical Performance Data**
  Performance testing included manometer accuracy, inflation and deflation functions, and absence of leaks. The performance testing includes a comparison between the VORTRAN® Cuff Inflator (VCI) and its predicate and reference devices, Posey Cufflator and Hospitech AG Cuffill.

- **Clinical Application**
  The VORTRAN® Cuff Inflator (VCI) connects to cuffed tubes (via a Luer fitting), which are used in applications in which a patient is intubated.

- **Compliance with Performance Standards**
  None

IX. CONCLUSIONS

The VORTRAN® Cuff Inflator (VCI) is substantially equivalent to predicate devices: Posey Cufflator (primary) and reference devices: Hospitech AG Cuffill, VORTRAN® Manometer (material only), and VORTRAN® Automatic Resuscitator (VAR-Plus) – (material only). The VORTRAN® Cuff Inflator (VCI) is concluded to not raise any different questions of safety and effectiveness in comparison to its predicate devices.