July 22, 2020

Venner Medical (Singapore) PTE Ltd
℅ Christine Brauer
Regulatory Affairs Consultant
Brauer Device Consultants, LLC
7 Trail House Court
Rockville, Maryland 20850

Re: K192511
Trade/Device Name: Venner PneuX™ TT (Tracheostomy Tube)
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube And Tube Cuff
Regulatory Class: Class II
Product Code: BTO
Dated: June 18, 2020
Received: June 19, 2020

Dear Christine Brauer:

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,

Todd Courtney
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)*
K192511

Device Name
Venner PneuX™ TT

Indications for Use *(Describe)*

The Venner PneuX™ TT (Tracheostomy Tube) is intended to be inserted into the patient's tracheostomy stoma during extended periods (not more than 30 days) of intensive or critical care to facilitate ventilation and for the evacuation or drainage of secretions from the subglottic space.

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

K192511

1 GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k)

Venner Medical (Singapore) Pte Ltd
35 Joo Koon Circle
Singapore 629110
Establishment Registration: 3007740622

1.2 Official Correspondent

Christine L. Brauer, PhD
Regulatory Affairs Consultant
Brauer Device Consultants, LLC
7 Trail House Court
Rockville, MD 20850

Telephone: (301) 545-1990
E-mail: chris.brauer@comcast.net

1.3 Devices Subject of this 510(k)

Venner Product Code	Trade Name	Product Size
902170	Venner PneuX™ TT (Tracheostomy Tube)	7.0 mm
902180	Venner PneuX™ TT (Tracheostomy Tube)	8.0 mm
902190	Venner PneuX™ TT (Tracheostomy Tube)	9.0 mm

1.4 510(k) Number and Date of Preparation

Submission Number: K192511
Date of Preparation: 17 June 2020

2 NAME OF THE DEVICE AND CLASSIFICATION INFORMATION

2.1 Trade/Proprietary Name

Venner PneuX™ TT (Tracheostomy Tube)

2.2 Common/Usual Name

Tracheostomy Tube – Low Volume, Low Pressure, Cuff

2.3 Classification Information

Classification Information	
Trade Name:	Venner PneuX™ TT (Tracheostomy Tube)
Classification Regulation:	21 CFR 868.5800 - Tracheostomy Tube and Tube Cuff
Product Code:	BTO - Tube, tracheostomy (w/wo connector)
Class:	II
Panel:	Anesthesiology

3 PREDICATE DEVICE

The predicate device is as follows:

- Venner PneuX TT (Tracheostomy Tube) cleared via K100950 on July 13, 2010

4 DEVICE DESCRIPTION

The Venner PneuX TT (Tracheostomy Tube) is a disposable, sterile, single-patient, single-use device. It is a flexible, low volume and low pressure cuffed tracheostomy tube, which is reinforced with a Nitinol wire. The Venner PneuX TT may be used with the Venner PneuX TSM™ to monitor, maintain and regulate cuff pressure. The Venner PneuX TSM was cleared for marketing via 510(k) application K110631.

The Venner PneuX TT is available in three sizes (inner diameters: 7.0, 8.0 and 9.0 mm) and is MRI Conditional. Depth markings indicate the distance to the distal tip of the tube and a printed black line provides a means to orient the tube.

The device provides access to subglottic space by having three additional lumens running along the airway lumen. The three lumens are integrated into the tube wall ending just above the proximal end of the cuff for ease of suction. Connected to the suction tube and subglottic connector, it allows intermittent suctioning of secretions from the subglottic space, and irrigation.

A winged tube holder allows for securement with openings on each end for a head/neck strap to pass through. A fixation block secures the position of the tube to prevent unintended movement during use. A standard connector (15 mm) for universal attachment to a ventilator is present, as well as an inflation line to connect the cuff for inflation and deflation. A pilot balloon connects the cuff to provide an indication of the pressure within the cuff and the pilot

valve opens to allow free flow of air to the cuff for inflation or deflation when a Luer lock syringe is engaged. When the syringe is removed, the valve closes to prevent leakage of air and ensures the cuff is inflated.

The obturator fits in the airway tube of the TT and guides its placement. Its tip is designed to aid passage through the surgical opening of a tracheostomy stoma. The obturator also has a hole which allows a guidewire to pass through, if clinically required.

5 INDICATIONS FOR USE

Below is the indication for use for the Venner PneuX TT.

> *The Venner PneuX™ TT (Tracheostomy Tube) is intended to be inserted into the patient's tracheostomy stoma during extended periods (not more than 30 days) of intensive or critical care to facilitate ventilation and for the evacuation or drainage of secretions from the subglottic space.*

6 COMPARISON OF THE INDICATION FOR USE AND INTENDED USE BETWEEN THE VENNER PNEUX TT AND THE PREDICATE DEVICE

The Venner PneuX TT and the predicate device share the same intended use, including the same purpose, function, conditions of use, users, target patient populations, and patient contact (see **Table 1**).

Table 1. ***Summary of Intended Use of the Venner PneuX TT and the Predicate Device***

Characteristic	Venner PneuX TT (This Application)	Venner PneuX TT (K100950)
Classification Regulation	21 CFR 868.5800	21 CFR 868.5800
Product Code	BTO - Tube, tracheostomy (w/wo connector)	BTO - Tube, tracheostomy (w/wo connector)
Class	II	II
Indication for Use	*…is intended to be inserted into the patient's tracheostomy stoma during extended periods (not more than 30 days) of intensive or critical care to facilitate ventilation and for the evacuation or drainage of secretions from the subglottic space*	*…intended to be inserted into the patient's trachea via a tracheostomy stoma during extended periods (not more than 30 days) of intensive or critical care to facilitate ventilation and for evacuation or drainage of secretion from the subglottic space*

Characteristic	Venner PneuX TT (This Application)	Venner PneuX TT (K100950)
Purpose	To establish and maintain an airway in patients who require ventilation due to illness or trauma or because the airway is blocked	To establish and maintain an airway in patients who require ventilation due to illness or trauma or because the airway is blocked
Function	Provides a physical conduit for gases to flow between a patient's lungs and a ventilator Connects to a ventilator Provides a means to remove secretions	Provides a physical conduit for gases to flow between a patient's lungs and a ventilator Connects to a ventilator Provides a means to remove secretions
Target Population	Adult patients requiring a tracheostomy	Adult patients requiring a tracheostomy
Target User	Health care professionals trained in airway management	Health care professionals trained in airway management
Prescription Device	Yes	Yes
Intended for Use in Clinical Environment	Yes	Yes
Body Contact	Surface-contacting mucosal tissue - Positioned in the trachea	Surface-contacting mucosal tissue - Positioned in the trachea
Compatible for Use with the Venner PneuX TSM™ (K110631)	Yes, connects to the Venner PneuX TSM via the Venner PneuX Extension Tube	Yes, connects to the Venner PneuX TSM via the Venner PneuX Extension Tube

7 COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Venner PneuX TT and the predicate share many of the same technological characteristics although there are some differences (see **Table 2**). Both systems are multi-lumen, with low volume, low pressure cuffs, and compatible for use with the Venner PneuX TSM.

Both are wire-reinforced tubes although different materials are used for the wire. In the modified Venner PneuX TT, the wire is made from Nitinol, allowing the device to be MRI conditional whereas a stainless-steel wire is used in the predicate device. Other material changes have been made to the Venner PneuX TT compared to the predicate to support MRI

compatibility (pilot valve), to use phthalate (DEHP) free material (15 mm connector, fixation block and obturator tip), and for commercial reasons such as supplier preferences. In addition, a new component, a female luer made of polypropylene, has been added to the end of the subglottic line and the design of the winged tube holder has been modified as well for ergonomic reasons.

Table 2. Summary of Technological Characteristics Comparing the Venner PneuX TT and the Predicate Device

Technological Characteristic	Venner PneuX TT (This Application)	Venner PneuX TT (K100950)
Design		
Tube	Multi-lumen, flexible tube	Multi-lumen, flexible tube
Sizes - Inner Diameter (mm)	7, 8 and 9	7, 8, and 9
Cuff	Low volume Low pressure	Low volume Low pressure
Reinforced	Yes – Nitinol Wire	Yes – Stainless Steel Wire
Ports	Yes – Three subglottic ports for removal secretions	Yes – Three subglottic ports for removal secretions
Internal Tube Coating	Yes – Inhibit adhesion of biological material	Yes – Inhibit adhesion of biological material
Depth Markings	Yes	Yes
Fixation Block	Yes	Yes
Standard Connector (15 mm)	Yes	Yes
Compatible with Venner PneuX TSM	Yes	Yes
MRI Conditional	Yes	No
Sterile and Sterility Assurance Level	Yes 10^{-6}	Yes 10^{-6}
Single-Use	Yes	Yes
Tissue Contact	Surface contacting – Trachea	Surface contacting – Trachea
Duration of Use	Up to 30 days	Up to 30 days
Materials		
Multi-lumen, tube	Silicone	Silicone
Wire for Reinforcement	Nitinol (MRI Conditional)	Stainless Steel
15 mm Connector	Polycarbonate (DEHP-free)	Polycarbonate
Subglottic Line	Silicone	Silicone
Subglottic Connector	Silicone	Silicone
Female Luer	Polypropylene	N/A
Reservoir	Silicone	Silicone
Inflation Line	Silicone	Silicone

Technological Characteristic	Venner PneuX TT (This Application)	Venner PneuX TT (K100950)
Pilot Balloon	Silicone	Silicone
Pilot Valve (Check Valve)	Polypropylene (MRI Conditional)	Polypropylene
Lock Nut	Polypropylene	Polyoxymethylene copolymer
Winged Tube holder	Silicone	Silicone
Fixation Block	Polycarbonate (DEHP-free)	Polycarbonate
Cuff	Silicone	Silicone
Obturator Rod	Stainless Steel ANSI 304V	Stainless Steel ANSI 304V
Obturator Handle	Polypropylene Blue	Polypropylene Blue
Obturator Tip	Polypropylene Natural (DEHP-free)	Polyvinylchloride

8 PERFORMANCE DATA

This 510(k) notification provided performance data to establish the substantial equivalence of the Venner PneuX TT.

Sterilization, Shelf Life and Packaging Integrity: The Venner PneuX TT is provided sterile for single patient use. The device is sterilized using ethylene oxide (EO) to a sterility assurance level (SAL) of 10^{-6}. The sterilization validation was performed in conformance to ISO 11135:2014 Sterilization of Health-Care Products - Ethylene Oxide - Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices, using the half-cycle approach. Ethylene oxide residue levels were evaluated to demonstrate that the device meets the tolerable contact limit (TCL) for prolonged exposure devices (patient contact for more than 24 hours and up to 30 days) for residues according to ISO 10993-7. Accelerated and real time aging studies support the proposed shelf life, including the packaging integrity.

Biocompatibility: Biocompatibility evaluation has been performed to show the device materials are safe, biocompatible and suitable for their intended use. Both ISO 10993 and FDA Guidance "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" have been taken into account to evaluate the biocompatibility of the device materials. The following biocompatibility studies were successfully completed with the Venner PneuX TT.

Table 3. Summary of the Biocompatibility Tests and Results

Test Performed	Test Method	Test Results
MEM Elution Assay (Cytotoxicity)	ISO 10993-5:2009 ISO 10993-12:2012	Pass
Intracutaneous Reactivity	ISO 10993-10:2010 ISO 10993-12:2012	Pass

Test Performed	Test Method	Test Results
Guinea Pig Maximum Sensitization	ISO 10993-10:2010 ISO 10993-12:2012	Pass
Acute Systemic Toxicity	ISO 10993-11:2006 ISO 10993-12:2012	Pass
Subacute/subchronic Toxicity (14-day)	ISO 10993-11:2006 ISO 10993-12:2012	Pass
Genotoxicity – Ames and Mouse Lymphoma Assay	ISO 10993-3:2014 ISO 10993-12:2012	Pass
Implantation (4-week)	ISO 10993-6:2007	Pass
Material-Mediated Pyrogenicity	ISO 10993-11:2006 ISO 10993-12:2012	Pass

Performance Testing: Performance testing was performed to characterize the Venner PneuX TT, including mechanical and functional testing, MRI compatibility testing and compliance to the standards ISO 5366:2016 Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors and ISO 5361: 2016 Anaesthetic and respiratory equipment — Tracheal tubes and connectors. The Venner PneuX TT has been tested in accordance with the ISO standards for dimensions, curvature, cuff diameter, and connectors. The Venner PneuX TT met the standard.

The Venner PneuX TT was evaluated in accordance with the standards for mechanical and functional requirements, and met the standard. This evaluation included an analysis of cuff leakage, cuff herniation, tube collapse, radiopacity, kink resistance, 15mm connector leakage and seal pressure leakage. Terminally sterilized unaged and aged samples were tested. The Venner PneuX TT both unaged and aged met the standard, supporting the 1-year shelf life. In addition, the following mechanical tests were performed: cuff inflation, leakage and function, lumen function, pull tests for all joints and connections, and bite block resistance. The device successfully passed each test, meeting its performance specifications.

The Venner PneuX TT was compared to the predicate device for the functional and mechanical tests and met the same acceptance criteria as the predicate device, demonstrating substantial equivalence.

For MRI compatibility, the device was evaluated for MRI compatibility in accordance with the FDA guidance document entitled “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment – Guidance for Industry and Food and Drug Administration Staff” issued on December 11, 2014. The following types of tests were performed: magnetically induced displacement force, magnetically induced torque, heating by radiofrequency fields and image artifact. The testing demonstrated that the device is MR compatible under the conditions identified in the device labeling (instructions for use).

9 CONCLUSIONS

Based on the comparison, biocompatibility testing, and performance testing, it has demonstrated that the subject device is substantially equivalent to the proposed predicate. The subject device has the same intended use as the predicate device and the differences in technological features do not raise different questions of safety and effectiveness