February 14, 2020

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

Re: K192120
Trade/Device Name: Venner PneuX™ ETT
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: January 7, 2020
Received: January 8, 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)*
K192120

Device Name
Venner PneuX™ ETT

Indications for Use *(Describe)*

The Venner PneuX™ ETT (Endotracheal Tube) is intended to be used for patients undergoing tracheal intubation during routine anesthesia or over extended periods (not more than 30 days) and for the evacuation or drainage of secretion 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
K192120

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
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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	Tradename	Product Size
901160	Venner PneuX™ ETT (Endotracheal Tube)	6.0 mm
901170	Venner PneuX™ ETT (Endotracheal Tube)	7.0 mm
901180	Venner PneuX™ ETT (Endotracheal Tube)	8.0 mm
901190	Venner PneuX™ ETT (Endotracheal Tube)	9.0 mm

1.4 510(k) Number and Date of Preparation

Submission Number: K192120
Date of Preparation: 05 January 2020

2 NAME OF THE DEVICE AND CLASSIFICATION INFORMATION

2.1 Trade/Proprietary Name

Venner PneuX™ ETT (Endotracheal Tube)

2.2 Common/Usual Name

Endotracheal Tube – Low Volume, Low Pressure, Cuff

2.3 Classification Information

General Information	
Trade Name:	Venner PneuX™ ETT (Endotracheal Tube)
Classification Regulation:	21 CFR 868.5730 Tracheal Tube
Product Code:	BTR - Tube, tracheal (w/wo connector)
Class:	II
Panel:	Anesthesiology

3 PREDICATE DEVICE

The predicate device is as follows:

- Venner PneuX ETT (Endotracheal Tube) cleared via K093135 on May 24, 2010

4 DEVICE DESCRIPTION

The Venner PneuX ETT (Endotracheal Tube) is a disposable, sterile, single-patient, single-use device. It is a straight, flexible cuffed (low volume, low pressure) Nitinol wire-reinforced tracheal tube with a Murphy Eye. When a patient is intubated with a Venner PneuX ETT and inflated by standard techniques, it can be attached to the Venner PneuX TSM™ via the Venner PneuX™ Extension Tube, to monitor, maintain and regulate cuff pressure. The Venner PneuX TSM, a cuff pressure controller, was cleared for marketing via 510(k) application K110631 and the Venner PneuX Extension Tube is a class I, 510(k) exempt device.

The Venner PneuX ETT is available in four sizes (inner diameters: 6.0, 7.0, 8.0 and 9.0 mm) and is MRI compatible. 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. An integrated bite block with fixation block provides a protective covering and secures the position of the tube to prevent unintended movement during use. A standard connector (15 mm) for universal attachment to a ventilator or anesthesia equipment 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.

5 INDICATIONS FOR USE

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

> *The Venner PneuX™ ETT (Endotracheal Tube) is intended to be used for patients undergoing tracheal intubation during routine anesthesia or over extended periods (not more than 30 days) and for the evacuation or drainage of secretion from the subglottic space.*

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

The Venner PneuX ETT 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 ETT and the Predicate Device***

Characteristic	Venner PneuX ETT (This Application)	Venner PneuX ETT (K093135)
Classification Regulation	21 CFR 868.5730	21 CFR 868.5730
Product Code	BTR - Tube, tracheal (w/wo connector)	BTR - Tube, tracheal (w/wo connector)
Class	II	II
Indication for Use	… is intended to be used for patients undergoing tracheal intubation during routine anesthesia or over extended periods (not more than 30 days) and for the evacuation or drainage of secretion from the subglottic space.	…intended to be used for patients undergoing tracheal tube intubation during extended periods (not more than 30 days) and for evacuation or drainage of secretion from the subglottic space. It is also compatible with tracheal intubation during routine anesthesia.
Purpose	To intubate patients during routine anesthesia To intubate patients for extended durations but not more than 30 days	To intubate patients during routine anesthesia To intubate patients for extended durations but not more than 30 days

Characteristic	Venner PneuX ETT (This Application)	Venner PneuX ETT (K093135)
Function	To maintain the airway so that gases can flow between a patient's lungs and a ventilator or anesthesia equipment To provide positive pressure ventilation To support breathing in critically ill patients To protect the lungs from aspiration	To maintain the airway so that gases can flow between a patient's lungs and a ventilator or anesthesia equipment To provide positive pressure ventilation To support breathing in critically ill patients To protect the lungs from aspiration
Target Population	Adult patients undergoing endotracheal intubation Adult patients who are severely ill and experiencing breathing difficulties	Adult patients undergoing endotracheal intubation Adult patients who are severely ill and experiencing breathing difficulties
Target User	Health care professionals trained in intubation	Health care professionals trained in intubation
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 ETT and the predicate share many of the same technological characteristics although there are some differences (see **Table 2**). Both systems are multi-lumen, straight endotracheal tubes 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 ETT, the wire is made from Nitinol, allowing the device to be MRI compatible whereas a stainless-steel wire is used in the predicate device. Other material changes have been made to the Venner PneuX ETT compared to the predicate to support MRI compatibility (pilot valve), to use phthalate (DEHP) free material (15 mm connector and integrated bite block with fixation block), 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 ETT and the Predicate Device

Technological Characteristic	Venner PneuX ETT (This Application)	Venner PneuX ETT (K093135)
Design		
Straight	Yes – Multi-lumen, straight tube	Yes – Multi-lumen straight tube
Sizes - Inner Diameter (mm)	6, 7, 8 and 9	6, 7, 8, and 9
Cuff	Low volume Low pressure	Low volume Low pressure
Tip Design	Boat Tip	Boat Tip
Murphy Eye	Yes	Yes
Reinforced	Yes – Nitinol Wire	Yes – Stainless Steel Wire
Ports	Yes – Three subglottic ports for removal secretions and irrigation	Yes – Three subglottic ports for removal secretions and irrigation
Internal Tube Coating	Yes – Inhibit adhesion of biological material	Yes – Inhibit adhesion of biological material
Depth Markings	Yes	Yes
Integrated Bite Block	Yes – Integrated with Fixation Block	Yes
Standard Connector (15 mm)	Yes	Yes
Compatible with Venner PneuX TSM	Yes	Yes
MRI Compatible	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, straight tube	Silicone	Silicone
Wire for Reinforcement	Nitinol (MRI compatible)	Stainless Steel
15 mm Connector	Polycarbonate (DEHP-free)	Polycarbonate
Subglottic Line	Silicone	Silicone
Subglottic Connector	Silicone	Silicone

Technological Characteristic	Venner PneuX ETT (This Application)	Venner PneuX ETT (K093135)
Female Luer	Polypropylene	N/A
Reservoir	Silicone	Silicone
Inflation Line	Silicone	Silicone
Pilot Balloon	Silicone	Silicone
Pilot Valve (Check Valve)	Polypropylene (MRI compatible)	Polypropylene
Lock Nut	Polypropylene	Polyoxymethylene copolymer
Winged Tube holder	Silicone	Silicone
Integrated Bite Block with Fixation Block	Polycarbonate (DEHP-free)	Polycarbonate
Cuff	Silicone	Silicone
Boat Tip with Murphy Eye	Silicone	Silicone

8 PERFORMANCE DATA

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

Sterilization, Shelf Life and Packaging Integrity: The Venner PneuX ETT 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 Venner PneuX ETT 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 ETT.

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

Test Performed	Test Method	Test Results
Intracutaneous Reactivity	ISO 10993-10:2010 ISO 10993-12:2012	Pass
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	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 ETT, including mechanical and functional testing, MRI compatibility testing and compliance to the standard ISO 5361: 2016 Anaesthetic and respiratory equipment — Tracheal tubes and connectors.

The Venner PneuX ETT has been tested in accordance with the standard ISO 5361: 2016 for dimensions, including bevel angle, curvature, cuff diameter, connectors and murphy eye size/placement. The Venner PneuX ETT met the standard.

The Venner PneuX ETT was evaluated in accordance with the standard ISO 5361:2016 for the following 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 ETT 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 ETT 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 predicate device, and does not raise different questions of safety and effectiveness