August 2, 2019

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

Re: K191602
Trade/Device Name: APA Oxy Blade
Regulation Number: 21 CFR 868.5540
Regulation Name: Rigid Laryngoscope
Regulatory Class: Class I
Product Code: CCW
Dated: June 14, 2019
Received: June 17, 2019

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)*
K191602

Device Name
APA Oxy Blade™

Indications for Use *(Describe)*

The APA Oxy Blade™ is a multi-functional, single-use, disposable larynoscope blade intended to assist in direct and indirect laryngoscopy and to facilitate and aid in tracheal intubation in routine and difficult airways in adult patients. The APA Oxy Blade™ incorporates an oxygen tube adaptor and tubing to provide supplemental oxygen to the patient while undergoing endotracheal intubation.

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.

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510(k) SUMMARY

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 Description
700330	APA Oxy Blade™	APA™ O_2 MAC 3 Blade
700340	APA Oxy Blade™	APA™ O_2 MAC 4 Blade

1.4 510(k) Number and Date of Preparation

Submission Number: K191602
Date of Preparation: 14 June 2019

2 NAME OF THE DEVICE AND CLASSIFICATION INFORMATION

2.1 Trade/Proprietary Name

APA Oxy Blade™ (APA™ O_2 MAC 3 and APA™ O_2 MAC 4)

2.2 Common/Usual Name

MacIntosh Laryngoscope Blade

2.3 Classification Information

Classification Information	
Classification Regulation:	21 CFR 868.5540 - Rigid Laryngoscope
Product Code:	CCW - Rigid Laryngoscope
Class:	I
Panel:	Anesthesiology

3 PREDICATE DEVICE

The predicate devices are as follows:

- Primary Predicate- Venner Medical APA MAC Blade, a class I, 510(k) exempt device
- Secondary Predicate- Vyaire Medical Airlife Oxygen Supply Tubing, a class I, 510(k) exempt device

Two predicate devices were selected in accordance with Section IV.C.1 of the guidance document entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] - Guidance for Industry and Food and Drug Administration Staff" dated July 28, 2014.

4 DEVICE DESCRIPTION

The APA Oxy Blade is a laryngoscope blade intended to be used with the Venner Medical APA™ Video Laryngoscope. The APA Oxy Blade is a standard MacIntosh laryngoscope blade with the addition of an oxygen tube adaptor/holder and tubing to provide supplemental oxygen to the patient when using the Venner APA Video Laryngoscope. The Venner APA Video Laryngoscope, like other rigid laryngoscopes, provides a clear view of the upper airway (trachea/airway) and aids in the placement of an endotracheal tube for intubation.

5 INDICATIONS FOR USE

Below is the indication for use for the APA Oxy Blade.

> *The APA Oxy Blade™ is a multi-functional, single-use, disposable laryngoscope blade intended to assist in direct and indirect laryngoscopy and to facilitate and aid in tracheal intubation in routine and difficult airways in adult patients. The APA Oxy Blade™ incorporates an oxygen tube adaptor and tubing to provide supplemental oxygen to the patient while undergoing endotracheal intubation.*

6 COMPARISON OF THE INDICATION FOR USE AND INTENDED USE BETWEEN THE APA OXY BLADE AND THE PREDICATE DEVICES

The APA Oxy Blade and the predicate APA MAC Blade share the same intended use, including the same purpose, function, conditions of use, users, target patient populations, and patient contact although there are slight variations in the indication for use statements (see table). The APA Oxy Blade and the Vyaire Medical Airlife Oxygen Supply Tubing device also share the same intended use, including the same purpose, function, conditions of use, users, target patient populations and patient contact. An indication for use statement was not available for the Vyaire Medical Airlife Oxygen Supply Tubing, likely reflecting the fact that the intended use and use of this simple, class I, 510(k) exempt device is commonly known and exempt from the requirements for adequate directions for use (21 CFR 801.116). Notwithstanding this, it clear that the APA Oxy Blade and the Vyaire Medical Airlife Oxygen Supply Tubing share the same intended use of oxygen delivery to patients.

Table 1. Summary of Intended Use of the APA Oxy Blade™ and the Predicate Device, the APA MAC Blades

Characteristic	APA Oxy Blade (This Application)	APA MAC Blade (510(k) Exempt)	Airlife Oxygen Supply Tubing (510(k) Exempt)
Classification Regulation	21 CFR 868.5540	21 CFR 868.5540	21 CFR 868.5860
Product Code	CCW – Rigid Laryngoscope	CCW – Rigid Laryngoscope	BYX – Tubing Pressure and Accessories
Class	I	I	I
Indication for Use	… to assist direct and indirect laryngoscopy… …to facilitate and aid in tracheal intubation… …to provide supplemental oxygen	…to assist direct and indirect laryngoscopy… …to facilitate endotracheal intubation…	---
Purpose	To facilitate and aid in placement of an endotracheal tube for intubation To view the larynx To provide supplemental oxygen	To facilitate and aid in placement of an endotracheal tube for intubation To view the larynx	To provide supplemental oxygen
Function	Lifts or displaces epiglottis out of the visual pathway to expose the laryngeal inlet to facilitate endotracheal tube placement	Lifts or displaces epiglottis out of the visual pathway to expose the laryngeal inlet to facilitate endotracheal tube placement	Provides supplemental oxygen

Characteristic	APA Oxy Blade (This Application)	APA MAC Blade (510(k) Exempt)	Airlife Oxygen Supply Tubing (510(k) Exempt)
	Provides supplemental oxygen		
Target Population	Adult patients undergoing endotracheal intubation who may require supplemental oxygen	Adult patients undergoing endotracheal intubation	Patients requiring supplemental oxygen
Target User	Health care professionals trained in intubation	Health care professionals trained in intubation	Health care professionals
Prescription Device	Yes	Yes	Yes
Intended for Use in Clinical Environment	Yes	Yes	Yes
Body Contact	Surface contacting	Surface contacting	Surface contacting

7 COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The APA Oxy Blade and the predicate device, the APA MAC Blade, share many of the same technological characteristics (see Table 2). Both systems are curved rigid laryngoscope blades, referred to as the MacIntosh design. Both are used to assist in endotracheal intubation by lifting or displacing the epiglottis, and to allow for visualization of the larynx. Both share the same dimensions and materials. Both are provided non-sterile for single-patient use and have the same tissue contact.

Table 2. Summary of Technological Characteristics Comparing the APA Oxy Blade™ to the APA™ MAC Blade

Technological Characteristic	APA Oxy Blade (This Application)	APA MAC Blade (510(k) Exempt)
Design	Curve laryngoscope blade – MacIntosh Adaptor of holder on blade to secure tubing	Curve laryngoscope blade – MacIntosh
Use	Attached to laryngoscope to assist in endotracheal intubation when continuous oxygen delivery deemed appropriate by health care professional	Attached to laryngoscope to assist in endotracheal intubation
Recommended Laryngoscope	Yes – Venner Medical APA Video Laryngoscope	Yes – Venner Medical APA Video Laryngoscope
Components for Oxygen Delivery	Yes – Tubing for oxygen delivery	No
Size	MAC 3 Blade: 12.2 x 3.8 x 3.5 cm MAC 4 Blade: 15.3 x 3.8 x 3.6 cm	MAC 3 Blade: 12.2 x 3.8 x 3.5 cm MAC 4 Blade: 15.3 x 3.8 x 3.6 cm
Material Composition	Blade: Polycarbonate Tubing: Polyvinylchloride	Blade: Polycarbonate

Technological Characteristic	APA Oxy Blade (This Application)	APA MAC Blade (510(k) Exempt)
Sterile	No	No
Single Use	Yes	Yes

The primary difference between the two MacIntosh blades is the addition of the tubing for oxygen delivery in the APA Oxy Blade. Therefore, the APA Oxy Blade has been compared to the Vyaire Medical Airlife Supply Tubing with respect to technological characteristics and shown to be substantially equivalent (see table).

Table 3. Summary of Technological Characteristics Comparing the APA Oxy Blade™ to the Vyaire Medical Airlife Oxygen Supply Tubing

Technological Characteristic	APA Oxy Blade (This Application)	Vyaire Medical Airlife Oxygen Supply Tubing (510(k) Exempt)
Design	Tubing with coupling to attach to oxygen supply	Tubing with coupling to attach to oxygen supply
Use	Delivers supplemental oxygen to patient Connects to oxygen supply	Delivers supplemental oxygen to patient Connects to oxygen supply
Size	Length: 4 meters	Length: 7-50 meters
Material Composition	Polyvinylchloride	Polyvinylchloride
Sterile	No	No
Single Use	Yes	Yes

8 PERFORMANCE DATA

This 510(k) notification provided performance data to establish the substantial equivalence of the APA Oxy Blade.

Packaging Integrity: The results from testing were provided to demonstrate the suitability and integrity of the packaging materials to protect the APA Oxy Blade. Packaging was assessed by visual inspections, pouch seal strength and the dye penetration testing. Devices were assessed by visual inspection and functional tests; all devices and pouches passed the tests. The packaging is suitable for its use.

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 APA Oxy Blade and/or

extracts thereof. In the completed studies, the materials were observed to be non-toxic, non-irritating and non-sensitizing according to the study protocols.

Table 4. Summary of the Biocompatibility Tests and Results

Test Performed	Test Method	Test Results
ISO MEM Elution Assay (Cytotoxicity)	ISO 10993-5:2009 ISO 10993-12:2012	Pass
ISO Intracutaneous Reactivity	ISO 10993-10:2010	Pass
ISO Guinea Pig Maximum Sensitization	ISO 10993-10:2010 ISO 10993-12:2012	Pass
ISO Acute Systemic Toxicity	ISO 10993-11:2017	Pass

Performance Testing: Performance testing was performed to characterize the APA Oxy Blade, including dimensional, mechanical and functional testing.

- Dimensional Specifications: The APA Oxy Blade met its dimensional specifications in both sizes.
- Functional Testing: Functional testing included anti-fog testing and flow rate testing using standardized test methods and prospectively identified acceptance criteria. All blades successfully passed the anti-fog test with no fogging observed. All devices successfully passed the flow test and met the acceptance criterion of ≥ 15 L/min.
- Mechanical Testing: The mechanical integrity of the APA Oxy Blade was evaluated in three separate tests to confirm the mechanical integrity of the connections of the various components. The tests included: diffuser and tube pull test, tube coupling and tube pull test, and simulation tensile test (blade to adaptor and adaptor to diffuser). In addition, air-leak testing was performed to evaluate the connection between the blade and the tubing. Standardized test methods and prospectively identified acceptance criteria were utilized. All devices successfully met the acceptance criteria for mechanical testing.

9 CONCLUSIONS.

Based on the comparison, biocompatibility testing, and performance testing, it has demonstrated that the subject device is substantially equivalent to the proposed predicates and does not raise different questions of safety and effectiveness.