DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 2, 2016

New Aera, Inc.
% Mr. Paul Dryden
Consultant
2400 Camino Ramon, Suite 365
Ramon, California 94583

Re: K152664
Trade/Device Name: Tidal Assist™ Ventilator (TAV™) System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: ONZ
Dated: October 31, 2016
Received: November 2, 2016

Dear Mr. Paul Dryden:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting Director
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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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K152664

Device Name

Tidal Assist™ Ventilator (TAV) System

Indications for Use *(Describe)*

The New Aera Tidal Assist™ Ventilator, with accessories, is a volume assist ventilator intended to aid adult patients with respiratory insufficiency. It is designed for patients who are capable of spontaneously breathing a minimum tidal volume of 3.5cc/kg of predicted body weight. The device is designed for continuous applications such as patient ambulation, physical therapy, occupational therapy, respiratory therapy, and other rehabilitation efforts in an institutional or home care environment. The device is intended for operation by trained personnel, patients or caregivers under the direction of a physician.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Official Contact:	New Aera, Inc. 2400 Camino Ramon, Suite 365 San Ramon, CA 94583 Todd Allum – Vice President of Engineering Tel – 925-322-0145
Proprietary or Trade Name:	Tidal Assist™ Ventilator (TAV™) System
Common/Usual Name:	Continuous ventilator
Classification Name/Code:	ONZ – continuous ventilator 21 CFR 868.5895, Class II
Device:	Tidal Assist™ Ventilator (TAV™) System
Predicate Device:	K131562 – Breathe Technologies – NIOV Ventilator (BT-V2S)
Reference Device:	K103392 – Chad Evolution Model OM-900

Device Description:
The New Aera Tidal Assist Ventilation (TAV) system comprises a small, lightweight, wearable, battery-powered ventilator, TAV-C100, and a nasal pillow interface, TAV-NP10. The system is intended to connect to an air or oxygen source and supports three modes of delivery:

- Tidal Assist mode, a breath-activated ventilation assist mode in which the delivered gas from the source entrains additional room air at the nasal pillows interface, delivering it under positive pressure during the patient's inhalation to assist breathing;
- Conserve mode, a breath-activated delivery mode used to conserve oxygen consumption when using a cylinder with regulator; and
- Constant mode, presenting a continuous 1 – 5 LPM flow of oxygen to the patient.

For the Tidal Assist mode, the user may select one of five flow delivery settings, corresponding to a delivered minute volume of approximately 1 – 5 LPM.

For the Conserve mode, the user may select one of five pulse delivery settings, corresponding to an equivalent gas flow rate of approximately 1 – 5 LPM.

For the Constant mode, the user may select one of five flow delivery settings, corresponding to a delivered gas flow rate of approximately 1 – 5 LPM.

The TAV system is battery operated, running from a single AA alkaline battery. Under typical usage, battery life is ~ 14 days; a low battery alert activates when battery life is less than 2 days under typical usage.

The system has a simple user interface, comprising:

- a mode selection button;
- buttons to increase or decrease the delivered flow rate;
- a button to turn the device on and off, and to temporarily silence any alarms;

- LED indicators for the current delivery mode, flow setting, and low battery and alarm conditions; and
- an audible buzzer used to alert the user to an alarm condition.

The device has two pneumatic ports:

- an inlet port, used to connect the regulated gas source to the device, and
- an outlet port, used to connect the device to the patient interface.

Lastly, the device has a bypass valve, used to deliver a constant 2 LPM gas flow rate to the patient in the event of a system failure.

Indications for Use:
The New Aera Tidal Assist™ Ventilator, with accessories, is a volume assist ventilator intended to aid adult patients with respiratory insufficiency. It is designed for patients who are capable of spontaneously breathing a minimum tidal volume of 3.5cc/kg of predicted body weight. The device is designed for continuous applications such as patient ambulation, physical therapy, occupational therapy, respiratory therapy, and other rehabilitation efforts in an institutional or home care environment. The device is intended for operation by trained personnel, patients or caregivers under the direction of a physician.

Patient Population: Patients who are spontaneously breathing with a minimum tidal volume of 3.5cc/kg of body weight.

Environments of Use: Home and institutional settings

Contraindications
The TAV System is not designed for patients who cannot spontaneously breathe or who are fully dependent on mechanical ventilation.

Summary of substantial equivalence
The proposed TAV System has been compared to the predicate Breathe Technologies Ventilator (BT-V2S) (K131562), see **Table 1**.

Attribute	Predicate Breathe Ventilator, BT-V2S K131562	Proposed TAV Systems
Device Classification & Product code:	Class II/ONZ	Class II/ONZ
Prescription Device:	Yes	Yes
Device Description:	The Predicate Ventilator, with accessories is a small, wearable, ventilator that interfaces with proprietary nasal and tracheostomy breathing circuits.	The New Aera Tidal Assist™ Ventilation (TAV) system, with accessories is a small, wearable, ventilator that interfaces with proprietary nasal breathing circuits.
Indications for Use:	The Breathe Technologies Ventilator, with accessories, is a volume assist ventilator intended to aid adult patients with respiratory insufficiency. It is designed for patients who are capable of spontaneously breathing a minimum tidal volume of 3.5cc/kg of predicted body weight. The device is designed for continuous applications such as patient ambulation, physical therapy, occupational therapy, respiratory therapy, and other rehabilitation efforts in an institutional or home care environment. The device is intended for operation by trained personnel, patients or caregivers under the direction of a physician.	The New Aera Tidal Assist™ Ventilator, with accessories, is a volume assist ventilator intended to aid adult patients with respiratory insufficiency. It is designed for patients who are capable of spontaneously breathing a minimum tidal volume of 3.5cc/kg of predicted body weight. The device is designed for continuous applications such as patient ambulation, physical therapy, occupational therapy, respiratory therapy, and other rehabilitation efforts in an institutional or home care environment. The device is intended for operation by trained personnel, patients or caregivers under the direction of a physician.
Technical Method:	The device consists of two components: a ventilator and a patient interface. The device is a light-weight, portable, electronically timed and controlled volume assist ventilator. The device delivers bolus volumes of 50-250ml. The device delivers augmented volumes that are blended in the interface, patient's airway and lung with ambient air provided by the patient's spontaneous breath	The device consists of three components: a regulator adapter, ventilator and a patient interface. The device is a light-weight, portable, electronically timed and controlled volume assist ventilator. The device delivers bolus volumes of 50-250ml. The device delivers augmented volumes that are blended in the interface, patient's airway and lung with ambient air provided by the patient's spontaneous breath
Method of Flow Control:	Electronically controlled proportional valve	Electronically controlled proportional valve
Delivered Gas:	Oxygen or air	Oxygen or air
Gas Supply Compatibility:	DISS 1240 connection	DISS 1240 connection and other compatible regulated oxygen or air sources.

Attribute	Predicate Breathe Ventilator, BT-V2S K131562	Proposed TAV Systems
Patient Interface and Delivery Method:	An interface with relatively large opening(s) through which the user can spontaneously breathe through. Pressurized nozzles are located within the interface to entrain ambient air through these openings during oxygen delivery in order to augment the delivered volume.	An interface with relatively large opening(s) through which the user can spontaneously breathe through. Pressurized nozzles are located within the interface to entrain ambient air through these openings during oxygen delivery in order to augment the delivered volume.
Trigger Sensitivity:	User adjustable fixed pressure setting	Preset relative flow trigger setting with signal artifact correction
Initiation of Bolus:	At onset of inhalation	At onset of inhalation
Bolus Delivery Phase:	During inhalation	During inhalation
Oxygen Bolus Size:	50 to 250ml	50 to 250ml
Breath Rate:	Up to 40 breaths/minute, patient triggered	Up to 40 breaths/minute, patient triggered
Additional Delivery Modes:	Not offered	Capable of delivering pulsed-dose oxygen (Conserve Mode), as well as continuous flow oxygen (Constant Mode).
Total Delivered Volume (oxygen and entrained ambient air):	The NIOV System delivers tidal volumes of up to 1,150 ml by providing positive inspiratory pressure with a maximum pressure up to 18 cmH_2O (Breathe Technologies PM-00-0057-A)	The TAV System delivers tidal volumes of up to 1,150 ml by providing positive inspiratory pressure with a maximum pressure up to 18 cmH_2O
Backup Mode:	Yes	Yes
Backup Rate:	3 LPM or 12 breaths/min	3LPM or 12 breaths/min
Alarms:	High Source Pressure (> 87 PSIG)	Pressure regulation system and High Flow Alarm
	High Delivery Pressure	High Flow Alarm
	High Circuit Pressure	Low Flow Alarm
	High PEEP Pressure	System Fault Alarm High Flow Alarm
	Low Source Pressure (< 41 PSIG)	Low Flow Alarm
	Low Delivery Pressure	Low Flow Alarm
	High Temperature	None
	System Fault	System Fault
	Breath Time Out: 20 or 60 seconds **Low Breath Rate:** 4 breaths/min **High Breath Rate:** 5 to 120 breaths/min	**Breath Time Out:** 20 seconds **Low Breath Rate:** 4 breaths/min **High Breath Rate:** 21 to 120 breaths/min

Attribute	Predicate Breathe Ventilator, BT-V2S K131562	Proposed TAV Systems
Battery Alarm:	Low Battery (< 25%, or ~1 hour remaining)	Low Battery (~2 days remaining)
Battery:	Internal, rechargeable	AA Alkaline, user replaceable
Battery duration:	4 hours, nominal use	14 days, nominal use
Weight:	1lb	3.8 oz
Length:	7.5”	4.8”
Width:	3.1”	2.4”
Thickness:	1.3”	0.9”
Pillows Interface size options	Multiple sizes	Universal size
Standards:	IEC 60601-1 IEC 60601 - 2- 12 ASTM F1100-90 ASTM F1246-91	AAMI / ANSI ES60601-1:2005 IEC 60601-1-2: 2007 IEC 60601-1-8 IEC 60601-1-11 ISO 10651-6
Biocompatibility:	ISO 10993-1	ISO 10993-1 Cytotoxicity Sensitization Irritation Leachable / Extractables Risk Based Assessment VOC $PM_{2.5}$

In the table above we offer an explanation of the similarities and differences, if any, between the proposed device and the predicate. In summary,

Indications –

- The TAV System is indicated as a volume assist ventilator intended to aid adult patients with respiratory insufficiency. It is designed for patients who are capable of spontaneously breathing a minimum tidal volume of 3.5cc/kg of predicted body weight. The device is designed for continuous applications such as patient ambulation, physical therapy, occupational therapy, respiratory therapy, and other rehabilitation efforts in an institutional or home care environment. The device is intended for operation by trained personnel, patients or caregivers under the direction of a physician.
- **Discussion** – This is similar to the predicate - K131562 – Breathe Technologies – Ventilator BT-V2S.

Patient Population –

- It is intended for spontaneously breathing adults.
- **Discussion** – The patient population is similar to the predicate - K131562 – Breathe Technologies – Ventilator BT-V2S.

Environment of Use –

- For use in home and institutional settings
- **Discussion** – The environments of use and personnel are similar to the predicate K131562 – Breathe Technologies – Ventilator BT-V2S.

Technology –

- The TAV is an electronically controlled proportional valve which has a breath detection sensor that triggers oxygen flow. In connects to an oxygen or air source and the patient interface is a nasal interface. It includes a conserver feature which delivers a bolus upon inhalation. The TAV has a pulsed dose mode and a constant flow mode which the predicate does not.
- **Discussion** – As outlined in the table above the technology and device features are similar to the predicate - K131562 – Breathe Technologies – Ventilator BT-V2S.

Performance Specifications –

- The performance specifications of the TAV are similar to the predicate regarding bolus size, breath rate, and trigger sensitivity. Both devices include backup modes and rates, and similar alarms.
- **Discussion** – Comparison of performance supports similarities to the predicate - K131562 – Breathe Technologies – Ventilator BT-V2S and the reference device – K103392 – Chad Evolution Model OM-900.

Differences

The differences between the proposed and predicate relate to:

- Technology – TAV incorporates pulse-dose oxygen (conserve mode) and continuous flow oxygen (constant mode) which are not in the predicate, but are in the reference device. These additional modes are convenience features for the user.
- Patient interface – The TAV system only connects to the user via nasal pillows while the predicate can also be used with tracheostomy patients
- Trigger sensitivity – TAV incorporates a pre-set flow trigger setting with a signal artifact correction algorithm, whereas the predicate is user adjustable to a fixed threshold. Testing was performed which demonstrated that the TAV triggered consistently for all simulated patient conditions and provided equivalent volume support to that of the predicate device.
- Battery – The TAV uses a standard alkaline battery which lasts 14 days where the predicate has an internal rechargeable battery with a single charge for the predicate lasting 4 hours vs. 14 days for the TAV system
- Physical size – The TAV is smaller
- **Discussion** – as discussed in the above table, none of the differences raise new concerns when compared to the predicate for the intended use.

Non-clinical Performance Testing

We have performed a number of tests appropriate for the proposed device. These tests include:

Biocompatibility of Materials –

- The materials in patient contact have been tested as follows:
    - Controller – VOC and $PM_{2.5}$
    - Patient interface
        - ISO 10993-1 Cytotoxicity, Sensitization, Irritation, Leachable and Extractable with a risk based assessment.
- **Discussion –** The information supports the materials as biocompatible for their intended use.

Electrical, EMC, EMI testing –

- We have evaluated the proposed device per ANSI/AAMI/ES 60601-1, IEC 60601-1-2, and IEC 60601-1-11 the device performed as intended meeting the requirements.
- **Discussion –** The proposed device met the requirements of the standards.

Bench testing –

- Comparison of Total Delivered Volume between the proposed device and the predicate Comparison of Delivered Volume of the proposed device using oxygen versus air as a gas source
- Comparison of waveforms
- Additional testing included: Battery life and run-time, Alarms, Trigger Sensitivity, Back-up rate, Delivered volume in the different modes
- Shelf-life and Oxygen and Fire hazard testing
- Accelerated Aging
- Cleaning – pre- and post- performance
- **Discussion –** The proposed device was tested to assure that it meets its performance specifications. Upon completion of the tests, it was found to meet its performance requirements.

Usability –

We performed a usability study with two user groups – Healthcare Professionals (HCPs) and Lay Users (patients and caregivers). All participants, overall, were observed to perform critical tasks associated with the device and there were no instances of close calls or observed hazard-related use scenarios that could have resulted in significant patient or user harm.

Substantial Equivalence Conclusion

The sponsor demonstrated through performance testing and non-clinical testing that the proposed device is substantially equivalent to the predicate.