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

August 11, 2017

Breathe Technologies
% Craig Coombs
President
Coombs Medical Device Consulting, Inc.
1193 Sherman St.
Alameda, California 94501

Re: K170037
Trade/Device Name: Breathe Technologies Life2000™ Ventilation System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, NOU
Dated: July 3, 2017
Received: July 5, 2017

Dear Craig Coombs:

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,

Michael J. Ryan -S

for Lori Wiggins, MPT, CLT
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170037

Device Name

Breathe Technologies Life2000™ Ventilation System

Indications for Use *(Describe)*

The Breathe Technologies Life2000™ Ventilation System is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.

The Life2000 Ventilation System consists of the Life2000 Ventilator and the Life2000 Compressor.

The System is intended for use by qualified, trained personnel under the direction of a physician. Specifically, the System is applicable for adult patients who require the following types of ventilatory support:

- Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask).
- Assist/Control mode of ventilation.

The System is suitable for use in home and institutional settings and is not intended for ambulance or air transportation.

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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Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor:	Breathe Technologies 175 Technology Drive, Suite 100 Irvine, CA 92618 Tel: 949-988-7724 Contact: Samir Ahmad, Ph.D.
Correspondent Contact Information:	Craig Coombs President Coombs Medical Device Consulting, Inc 1193 Sherman St. Alameda, CA 94501 Office: 510.337.0140 Fax: 510.337.0416
Device Common Name:	Mechanical Ventilator
Device Classification & Name:	21 CFR 868.5895 Continuous Ventilator
Device Classification & Product Code:	Class II Primary: CBK; Secondary: NOU
Device Proprietary Name:	Breathe Technologies Life2000™ Ventilation System

Predicate Device Information:

Predicate Device:	Life2000 Ventilation System
Predicate Device Manufacturer:	Breathe Technologies, Inc.
Predicate Device Premarket Notification #	K141943
Predicate Device Common Name:	Continuous Ventilator
Predicate Device Classification & Name:	21 CFR 868.5895
Predicate Device Classification & Product Code:	Class II CBK

Reference Device Information:

Reference Device:	Compressor Mini
Reference Device Manufacturer:	Siemens
Reference Device Premarket Notification #	K023354
Reference Device Common Name:	Portable Air Compressor
Reference Device Classification & Name:	21 CFR 868.6250
Reference Device Classification & Product Code:	Class II BTI

Predicate Device Information:

Predicate Device:	Hybrid NE Mask
Predicate Device Manufacturer:	RespCare, Inc.
Predicate Device Premarket Notification #	K062019
Predicate Device Common Name:	Face Mask Accessory to Continuous Ventilator
Predicate Device Classification & Name:	21 CFR 868.5895
Predicate Device Classification & Product Code:	Class II CBK

b. Date Summary Prepared
2 August 2017

c. Description of Device
The Breathe Technologies Life2000 Ventilation System includes a portable, battery powered, continuous ventilator that was cleared in K141943 along with the Breathe Pillows Interface, Universal Connector and various other dedicated accessories.

In this submission, the Life2000 Ventilation System is expanding with the inclusion of additional components, including the Life2000 Compressor, a portable air compressor. This Life2000 Compressor provides a primary source of compressed air for the Life2000 Ventilator, in addition to the previously cleared gas sources of facility in-wall compressed gas (air & oxygen) and tanks of compressed medical gas. The Life2000 Compressor provides a dedicated docking station for the Life2000 Ventilator.

The Ventilator administers the physician-prescribed volume to the patient via the previously cleared Breathe Technologies Universal Connector which connects into the patient's tracheostomy tube, endotracheal tube, or any off the shelf non-invasive mask. It can also be used with the previously cleared Breathe Technologies Pillows Interface (K141943), a type of nasal mask.

This submission includes new versions of the Pillows Interface, labeled as the Breathe Pillows Entrainment Interface, that have an inlet for supplemental oxygen. It also includes labeling for the use of third party supplemental Oxygen Adapters for use with the Universal Connector. These inlets or Adapters allow the physician to administer supplemental oxygen into the patient circuit or interface.

d. Intended Use

The Breathe Technologies Life2000™ Ventilation System is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.

The Life2000 Ventilation System consists of the Life2000 Ventilator and the Life2000 Compressor.

The System is intended for use by qualified, trained personnel under the direction of a physician. Specifically, the System is applicable for adult patients who require the following types of ventilatory support:

- Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask).
- Assist/Control mode of ventilation.

The System is suitable for use in home and institutional settings and is not intended for ambulance or air transportation.

e. Comparison to Predicate Device

The Life2000 Ventilation System (Life2000 Ventilator + Accessories + Life2000 Compressor) is identical in Intended Use, Indications for Use, technology, performance, and environment of use to the Life2000 Ventilation System (Life2000 Ventilator + Accessories) that was cleared under K141943.

The Life2000 Ventilator, a component of the Life2000 Ventilation System, is fundamentally unchanged between the predicate and application Systems.

The Life2000 Compressor is included in this Life2000 Ventilation System 510(k) because it is a dedicated accessory for the Life2000 Ventilation System. The addition of the Life2000 Compressor as a source of compressed air for the Life2000 Ventilator raises no new questions of safety or efficacy. The Life2000 Compressor is referenced to the Siemens Compressor Mini (K023354) in regards to technology, technology application and use risk. This submission includes testing to support the conclusion that the Life2000 Compressor provides an adequate level of compressed air to the Life2000 Ventilator.

The oxygen inlets added to the previously cleared Breathe Pillows Interface are substantially equivalent in Intended Use, Indications for Use, technology and design as the oxygen inlet ports in the RespCare Hybrid NE Mask (K062019).

All supporting data demonstrate that the Life2000 Compressor is appropriate for its intended use within the Life2000 Ventilation System. All supporting data demonstrate the Breathe Pillows Entrainment Interface, and the use of third-party Oxygen Adapters in-line with the Universal Circuit Connector, are appropriate for their intended use within the Life2000 Ventilation System.

f. Summary of Supporting Data

The bench testing along with the electrical safety testing demonstrate that the Life2000 Compressor is an appropriate source of compressed gas for the Life2000 Ventilation System.

In particular, testing demonstrated that Life2000 Ventilation System is compliant with the following Guidelines and Standards:

- ISO 10993-1 (2009): Biological evaluation of medical devices -- Part 1: Evaluation and testing
  - Materials were identical to those used in an identical manner in previously cleared Breathe Technologies Ventilation Systems.
  - New particulate and volatile organic compound (VOC) testing was conducted for the Life2000 Compressor as a component of the Life2000 Ventilation System.

- FDA Draft Reviewer Guide for Ventilators (July 1995)

- ASTM F1246-91 (1991, Reapproved 2005); Standard Specification for Electrically Powered Home Care Ventilators, Part 1 – Positive Pressure Ventilators and Ventilator Circuits

- AAMI/ANSI 60601 – 1 (2005): Medical electrical equipment – General Requirements for Safety and Essential Performance

- IEC 60601-1-2 (2007) Medical Electrical Equipment, General Requirements for Basic Safety & Essential Performance: Electromagnetic Compatibility – Requirements & Test.

- ISO 80601-2-12 (2011), First Edition 2011-04-15, Medical electrical equipment -Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators.

- ISO 80601-2-72: 2015 Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients.

- IEC 62133 Edition 2.0 2012: Secondary Cells and Batteries Containing Alkaline or Other Non-Acid Electrolytes – Safety Requirements for Portable Sealed Secondary Cells, and for Batteries Made from Them, for Use in Portable Applications.

- IEC 62366: 2007: Medical devices - Application of usability engineering to medical devices.

- FDA Guidance Document: Design Considerations for Devices Intended for Home Use. Updated August 8, 2016.
  Additional EMC home level testing was performed per guidance.

- ANSI/AMEE HE75:2009: Human Factors Engineering-Design of Medical Devices.

- FDA Guidance Document: Medical Device Use Safety: Incorporating Human Factors Engineering into Risk Management, draft 2011.

- AIM 7351731: Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

g. Summary of Human Factors Data

A series of HFE/UE analyses, design refinement activities and Human Factors Validation (HFV) tests were conducted to evaluate the safe and effective use of the Life2000™ Ventilation System by its intended user populations in its intended use environments. The results of the HFV tests, included the testing of over 100 participants from 4 user groups:

- Patients
- Caregivers
- Respiratory Therapists
- Physicians and Critical Care Nurses

The test participants were evaluated under home and clinical simulated environments.

Human Factors validation revealed that representative participants were able to use the Life2000™ Ventilation System without use errors that could result in negative clinical outcomes. As a result of these HFE/UE studies, the Life2000™ Ventilation System has been found to be as safe and effective for the intended users, uses and use environments as the predicate Life2000 Ventilation System.

Breathe Technologies concludes that both clinicians and lay care-givers could properly operate the application Life2000 Ventilation System (Ventilator & Compressor) after receiving the required training and reading the Instructions for Use, just as was demonstrated with the predicate Life2000 Ventilation System.

Tabular Comparison: Application Life2000 Ventilation System to Predicate Life2000 Ventilation System.

	Predicate Device: Life2000 Ventilation System	Application Device: Life2000 Ventilation System	Difference Status
Indications for Use	The Breathe Technologies Life2000 Ventilation System is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult patients who require the following types of ventilatory support: - Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask). - Assist/Control mode of ventilation. The ventilator is suitable for use in home and institutional settings.	The Breathe Technologies Life2000™ Ventilation System is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The Life2000 Ventilation System consists of the Life2000 Ventilator and the Life2000 Compressor. The System is intended for use by qualified, trained personnel under the direction of a physician. Specifically, the System is applicable for adult patients who require the following types of ventilatory support: • Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask). • Assist/Control mode of ventilation. The System is suitable for use in home and institutional settings and is not intended for ambulance or air transportation.	Identical, except for the name change. In the predicate submission, the term "System" referred to only the Ventilator and its accessories. In the application device, the term "System" refers to the Ventilator and its accessories, including the Life2000 Compressor and modified Pillows Interface. The addition of the Compressor and the modified Pillows Interface does not change the intended use of the Ventilator.

	Predicate Device: Life2000 Ventilation System	**Application Device: Life2000 Ventilation System**	**Difference Status**
Product Classification Code	CBK	CBK & NOU	Identical. The addition of the Portable Air Compressor does not change the Ventilator System overall product code. The predicate System was cleared for home use, but the NOU procode was not added. This administrative oversight is being corrected in this submission.
Principal Operator	Trained personnel under the direction of a physician	Trained personnel under the direction of a physician	Identical
Environment of Use	Institution & Home	Institution & Home	Identical because this aspect of the Ventilation System is unchanged from the predicate
Patient Interface: General Description	Delivered invasively (via ET tube) or non-invasively (via mask).	Delivered invasively (via ET tube) or non-invasively (via mask).	Identical because this aspect of the Ventilation System is unchanged from the predicate.
Patient Interfaces Possible	Breathe Pillows Interface; Most 3rd party Masks attached via Breathe Universal Connector	Breathe Pillows Interface; Most 3rd party Masks attached via Breathe Universal Connector	Identical because this aspect of the Ventilation System is unchanged from the predicate
Port in Mask for Supplemental Oxygen?	Not Available with original Breathe Pillows Interface	Supplemental Oxygen port is added to the Breathe Pillow Interface to create the Breathe Pillow Entrainment Interface	The Supplemental Oxygen port in the Breathe Pillows Entrainment Interface allows for same Oxygen ranges as in predicate device
Type of Supply Gas To the Ventilator	Pressurized Oxygen or Air (50 psi)	Pressurized Oxygen or Air (50psi)	The ventilator in this application is identical to the predicate ventilator. Both use the same type of supply gas.

	Predicate Device: Life2000 Ventilation System	**Application Device: Life2000 Ventilation System**	**Difference Status**
Method of Delivering Supply Gas to the Ventilator	Compressed oxygen or air from tanks, or wall supply	Compressed oxygen or air from tanks, or wall supply or compressed room air from the Breathe Life2000 Compressor	The Life2000 Compressor is an additional device for supplying compressed air to the Ventilator
Power Source	The Ventilator is battery powered, it can be run while battery is charging	The Ventilator and Compressor are battery powered, they can be run while their batteries are charging	Identical because this aspect of the Ventilation System is unchanged from the predicate
Operational Modes	Volume Control Volume Assist/Control Volume Assist	Volume Control Volume Assist/Control Volume Assist	Identical because this aspect of the Ventilation System is unchanged from the predicate
Design Designation	Portable Continuous Care	Portable Continuous Care	Identical
Size WxLxH (in)	3.2 x 7.7 x 1.0 Ventilator only	12.1 x 8.7 x 8.6 Ventilator & dedicated Life2000 Compressor combined	Both Ventilators are identical. Both Systems are portable.
Weight	1.1 lbs Ventilator only	16 lbs: Ventilator & dedicated Life2000 Compressor combined	Both Ventilators are identical. Both are portable.
Volume Setting Range	50 – 750 ml/breath	50 – 750 ml/breath	Identical because this aspect of the Ventilation System is unchanged from the predicate.
Resultant Tidal Volume	50 - Up to 2000 ml/breath due to venturi effect	50 - Up to 2000 ml/breath due to venturi effect	Identical because this aspect of the Ventilation System is unchanged from the predicate
PEEP Setting	0 – 10 cmH2O	0 – 10 cmH2O	Identical because this aspect of the Ventilation System is unchanged from the predicate
PIP Alarms & Monitoring	Yes	Yes	Identical because this aspect of the Ventilation System is unchanged from the predicate
Adjustable Inspiration Time	0.15 to 3 seconds	0.15 to 3 seconds	Identical because this aspect of the Ventilation System is unchanged from the predicate

	Predicate Device: Life2000 Ventilation System	**Application Device: Life2000 Ventilation System**	**Difference Status**
Supply Gas	Oxygen, Air	Oxygen, Air	Identical because this aspect of the Ventilation System is unchanged from the predicate
Method of Supply Gas Pressurization	Compressed source for Air Compressed source for O2 (both from Facility or tank)	Compressed source for Air (from Facility Compressor, Life2000 Compressor or tank); Compressed source for O2 (From Facility Compressor or directly from an O2 Tank)	Equivalent Result (waveforms) independent of supply gas pressurization method.
Sterilized?	Ventilator: No Patient Circuit: No	Ventilator: No Patient Circuit: No	Identical because this aspect of the Ventilation System is unchanged from the predicate
Compressed Gas Requirements	41-87 psi	41-87 psi	Identical because this aspect of the Ventilation System is unchanged from the predicate
Compressor Output	None	Life2000 Compressor continuous output 17Lpm @ 50psi Maximum instantaneous output ~40Lpm @ 50 psi	Predicate did not have a dedicated Compressor. Nonetheless no new questions of Safety and Efficacy are raised because both Ventilators are designed to work with compressed air in the same way. Waveform data validates that Life2000 Compressor provides adequate output.

Tabular Comparison: Application Life2000 Compressor to Reference Device, the Compressor Mini (K023354)

Element Category or number	Reference Device: Siemens Compressor Mini	Application: Breathe Technologies Life2000 Compressor	Substantial Equivalence Discussion
1.	Electrical Powered Air Compressor	Electrical Powered Air Compressor	Equivalent
2	Air Inlet Filter	Air Inlet Filter	Identical functionality
3	Compressor with Motor (2 heads)	Compressor with motor (4 heads)	Identical functionality
4	Air Dryer: - Cooling coil - Thermoelectric cooler - Water Separator/collector	Air Dryer: - Membrane dryer - Mist separator/collector	The predicate's condensate method of drying is different from mechanically removing moisture from the gas with a Mist Separator/collector. Both end up with the same result, and both can accommodate the full range of flows from the specified Ventilator.
5	Pressure Regulation: - Pressure regulator - Tank - Safety Valve - Standby Valve	Pressure Regulation: - Pressure relief valve - Tank - Motor Speed	The predicate compressor generates excessive pressure which is moderated by the regulator before it enters the accumulator tank. The application compressor generates the proper pressure in the accumulator tank by a fixed motor/pump speed. Both have safety valves for excess pressure. The results are functionally identical and do not create new issues of safety or efficacy.
6	Room Air Inlet only	Room Air Inlet only	Identical functionality
7	Compressed Air outlet	Compressed Air Outlet	Identical functionality
8	Drainage Valve	Drainage valve	Identical functionality
9	Drainage bottle	Drainage bottle	Identical functionality
10	Dust Filter (for cooling)	Dust Filter (for cooling)	Identical functionality
11	Cooling Fans	Colling fans	Identical functionality
12	Power Inlet connector	Power Inlet connector	Identical functionality
13	ON/OFF switch	ON/OFF switch	Identical functionality
14	User Interface	User Interface	Identical functionality
15	Electrical Board	Electrical Board	Identical functionality

Element Category or number	**Reference Device: Siemens Compressor Mini**	**Application: Breathe Technologies Life2000 Compressor**	**Substantial Equivalence Discussion**
16	Alarms Temperature Pressure	Alarms: • High motor temperature • High electronics temperature • Electronics circuit error Motor Stall • Low and high pressure alarms (provided by the ventilator)	Application device has the same Alarms as the predicate, and has an additional Motor Stall alarm
17	Power Supply Mains	Power Supply 60 min battery Mains	Both can be connected to main power supply. Life2000 provides a backup battery option
18	Designed to supply only one ventilator at a time	Designed to supply only one ventilator at a time	Identical
19	Flow Output: 30 Liters/min	Continuous Flow Output: 17 L/min Peak Flow Output: 40 Liters/min	Outputs are functionally identical because they support a specified ventilator. The Life2000 Ventilator requires less flow from the Life2000 Compressor to allow the same outputs at the patient mask because the Ventilator entrains room air to augment the Compressor flow. Testing shows that the compressor can support the maximum volume output of the ventilator
20	Pressure Output 50 – 64 psi	Pressure Output: Nominal of 50 psi and range of 47 - 64 psi	Functionally identical
21	Ventilator Compatibility: Can be used with any Ventilator that meets its specifications	Ventilator Compatibility: Can only be used with the Life2000 Ventilator	Functionally identical for their specified Ventilators

Tabular Comparison: Application Breathe Pillows Entrainment Interface to Predicate Hybrid EV (K062019)

Component Number	Predicate: RespCare Hybrid NE Mask	Breathe Pillows Entrainment Interface with Oxygen Inlet	Substantial Equivalence Discussion
Indication for use:	The Hybrid NE Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators that have adequate alarms and safety systems for ventilator failure, and which are intended to administer positive pressure ventilation. The mask will be offered in a disposable version and a multiuse version. It is intended for use on adult patients (>30 kg), who are appropriate candidates for noninvasive ventilation. (Applies to the standard version): For homecare applications, the Hybrid NE Mask may be reused multiple times by a single patient. For institutional applications (i.e. hospital or other clinical settings), this interface may be reused multiple times by multiple patients. (Applies to the Disposable version): The RespCare Hybrid NE Mask Disposable is a single patient, single use interface.	The Breathe Pillows Entrainment Interface Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to the Breathe Life2000 Ventilation System. It is intended for use on adult patients who are appropriate candidates for noninvasive ventilation. The Pillows Interface is intended for use in hospital, institution and home environments. The mask may be reused multiple times by a single patient.	These Indications for Use are nearly identical. Both masks are intended to be used only with Ventilators that meet the specifications of the mask. Both are intended for the same cohort (adults) in the same environments of home, institutional and hospital. The Breathe mask does not come in a disposable version. As a result, the differences between masks do not raise new questions of safety or efficacy.
Technology			
Mask	Provides noninvasive interface between patient and Ventilator	Provides noninvasive interface between patient and Ventilator	Same
Oxygen Supplementation at the Mask	Yes	Yes	Same

Component Number	**Predicate: RespCare Hybrid NE Mask**	**Breathe Pillows Entrainment Interface with Oxygen Inlet**	**Substantial Equivalence Discussion**
Is Entrainment used to Supplement Air Volume from Ventilator?	No. All gas supplied to mask comes from Ventilator and supplemental oxygen inputted into the mask	Yes. Gas supplied to the mask comes from the Ventilator, supplemental oxygen inputted into the mask and from entrained air	Both devices provide a functionally equivalent output that is titrated to the patient's needs. Both masks can input supplemental oxygen into the gas stream from the Ventilator. This entrainment technology is identical to that cleared in the Breathe Interface Pillows mask in K141943.
Design			
Facial Interface	Mouth & Nose	Nose Only	The Breathe device provides adequate ventilation through the nose only just as the Hybrid Mask provides adequate ventilation through the Mouth and Nose. This interface is identical to the Breathe Pillows Interface cleared in K141943 This difference raises no new questions of safety and efficacy.
Sizes	Small Medium Large	Small Medium Large Extra Large	Both masks offer a range of sizes to fit a range of adult patients. The addition of a larger size in the Breathe mask does not accommodate a different cohort than the Hybrid device.
Materials			
Mask Body	Polycarbonate	Polycarbonate	Same
Nose Pillows	Silicone	Silicone	Same
Head Gear	Nylon, Neoprene, Velcro Hook & Loop	No head gear is needed with the Breathe interfaces (identical to K141943)	Same function achieved with the different methods of head attachment

Conclusion

Breathe Technologies concludes that the nonclinical and human factors tests demonstrate that the application Life2000 Ventilation System (Life2000 Ventilator + Life2000 Compressor, with accessories) is as safe, as effective, and performs as well as the predicate Life2000 Ventilation System (K141943).

Additionally, Breathe Technologies concludes that the nonclinical and human factors tests demonstrate that the application Breathe Pillows Entrainment Interface with an oxygen inlet for supplemental oxygen is as safe, as effective, and performs as well as the predicate RespCare Hybrid NE mask (K062019) when used as part of the patient circuit of the Life2000 Ventilation System.