Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor:	Breathe Technologies 175 Technology Drive, Suite 100 Irvine, CA 92618 Tel: 949-988-7700
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 ONZ
Device Proprietary Name:	Breathe Technologies NIOV Ventilation System

Predicate Device Information: Pending Clearance

Predicate Device:	Ventilator, BT-V2S
Predicate Device Manufacturer:	Breathe Technologies
Predicate Device Premarket Notification #	K103345
Predicate Device Common Name:	Mechanical Ventilator
Predicate Device Classification & Name:	21 CFR 868.5895
Predicate Device Classification & Product Code:	Class II ONZ

b. Date Summary Prepared
5 March 2014

c. Description of Device
The Breathe Technologies NIOV Ventilator System is a battery powered, wearable, volume ventilator that augments the patient's spontaneous breathing.

The NIOV Ventilator administers this physician-prescribed volume to the patient via the attached Breathe Technologies Patient Circuit (BT-PC) which inserts into the patient's tracheostomy tube, or via the Breath Technologies NIOV Pillows Interface, a type of nasal mask.

The ventilator is small and light enough to be worn on a patient's belt, or slung over their shoulder. It is connected to a separate, third party, air or oxygen gas supply.

The Ventilator is cleared for Institutional or Home Use.

d. Intended Use

The NIOV Ventilator, with accessories, is a volume assist ventilator intended to aid adult patients with respiratory insufficiency. It is designed for patients that are capable of spontaneously breathing a minimum tidal volume of 3.5 ml/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 their caregivers under the direction of a physician.

e. Comparison to Predicate Device

The Breathe Technologies NIOV Ventilator is substantially equivalent in Intended Use, Indications for Use, technology, design, and performance to the BT-V2S that was cleared under K103345. The ventilators' patient circuits are mechanically identical. They differ only in a few dimensions.

The modifications for the application device are described in part 1h of section 11. All the changes, except for the additional supply gas, would be considered a "Not Significant" change when judged by themselves according to the FDA memorandum "*Deciding when to Submit a 510(k) for a Change to an Existing Device, K97-1.*" Many have already been implemented per the justifications of the K97-1 memo.

None of the changes creates a change in the indications for use or a change in the fundamental scientific technology of the Breathe NIOV Ventilator.

Since only one of the modifications are significant per FDA guidelines, and the addition of air as a supply gas does not raise new questions of safety or effectiveness, the version of the Breathe NIOV Ventilator submitted in this application is substantially equivalent to the predicate version of the BT-V2S described in K103345.

Breathe Technologies concludes that based on intended use, performance and documentation the application NIOV Ventilator is substantially equivalent to the BT-V2S that was cleared under K103345.

f. Summary of Supporting Data

The Software Design and Validation process (Section 16) along with the bench testing of the device (Section 18) demonstrated that the Breathe NIOV Ventilator System operates as intended.

In particular, testing demonstrated that Breathe NIOV Ventilator System continues to be compliant with the following Guidelines and Standards:

- FDA Draft Reviewer Guide for Ventilators (July 1995)
- ASTM F1100 – 90 (1997), Standard Specification for Ventilators Intended for Use in Critical Care

- IEC 60601 – 1 (1988), Amendment 1 (1991-11), Amendment 2 (1995): Medical electrical equipment – General Requirements for Safety

- IEC 60601 – 2- 12 (2001-10); Medical electrical equipment – Particular requirements for the safety of lung ventilators – Critical care ventilators

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

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

March 6, 2014

Breathe Technologies
c/o Mr. Craig Coombs, President
Coombs Medical Device Consulting, Inc.
1193 Sherman St.
Alameda CA 94501

Re: K131562

Trade/Device Name: Breathe Technologies NIOV Ventilation System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: II
Product Code: ONZ
Dated: January 31, 2014
Received: February 3, 2014

Dear Mr. 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.

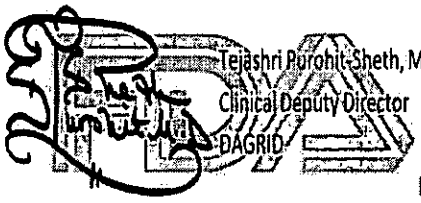
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



FOR

Erin I. Keith, M.S.
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 on last page.

510(k) Number *(if known)*
K131562

Device Name
Breathe Technologies NIOV Ventilation System

Indications for Use *(Describe)*
The NIOV Ventilator, with accessories, is a volume assist ventilator intended to aid adult patients with respiratory insufficiency. It is designed for patients that are capable of spontaneously breathing a minimum tidal volume of 3.5 ml/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 their 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)*

FDA
Anya C. Harry -S
2014.03.05
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