Section 5: 510(k) Summary

FEB 11 2011

Device Information:

Category	Comments
Sponsor:	Breathe Technologies 4000 Executive Parkway, Ste. 190 San Ramon, CA 94583 Tel: 925-359-1500
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:	Ventilator (BT-V2S)

Predicate Device Information:

Predicate Device:	Ventilator, BT-V2S
Predicate Device Manufacturer:	Breathe Technologies
Predicate Device Premarket Notification #	K102525
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

11 February 2011

c. Description of Device

The Breathe Technologies Ventilator with Accessories (BT-V2S) is a small, wearable, ventilator that interfaces with proprietary nasal and tracheostomy breathing circuits.

This application is being filed to clear the use of the BT-V2S in the Home Care Environment. The device is unchanged from the previous cited submissions, except for the layout and workflow of its User Interface, along with the various Instructions for Use necessary to ensure proper use by the patient or lay caregiver.

d. Intended 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.

e. Comparison to Predicate Device

The Breathe Technologies Ventilator (BT-V2S) is substantially equivalent in Intended Use, Indications for Use, technology, design, and performance to the BT-V2S that was cleared in a previous 510(k) (K102525). The predicate and application ventilators and patient circuits are mechanically identical.

The application BT-V2S's Indication for Home Use is supported by multiple Human Factors studies. These studies demonstrate that the application device works as described in its labeling, and is therefore substantially equivalent to its predicate.

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 BT-V2S operates as intended.

In particular, testing demonstrated that the BT-V2S 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

Additionally, three Human Factors Studies (Section 20) demonstrated that the intended users of the Ventilator (trained personnel, patients, or caregivers under the direction of a physician) can properly operate the device. The first study was with clinicians, and the second was with respiratory therapy patients. The third study demonstrated that the changes required in the training, Instructions for Use and User Interface were adequate to address the issues observed in the second study.

The Human Factors testing documented conformance with these external Guidelines/Standards:

FDA Guideline: Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management. July 18, 2000

IEC 62366: 2007: Medical devices - Application of usability engineering to medical devices. FDA Recognition Number 5-50.

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

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Joseph Cipillone
Vice President
Breathe Technologies, Incorporated
4000 Executive Parkway, Suite 190
San Ramon, California 94583

FEB 11 2011

Re: K103345
Trade/Device Name: Breathe Technologies Ventilator (BT-V2S) with Accessories
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: ONZ
Dated: November 11, 2010
Received: November 15, 2010

Dear Mr. Capillone:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known):

Device Name: Breathe Technologies Ventilator (BT-V2S) with Accessories

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.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of _____

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103345