K100528

APR 23 2010

Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor:	Breathe Technologies 4000 Executive Parkway, Ste. 190 San Ramon, CA 94583 Tel: 925-359-1500
Correspondent Contact Information:	Suzon Lommel Breathe Technologies 4000 Executive Parkway, Ste. 190 San Ramon, CA 94583 Tel: 925-359-1508 Fax: 925-886-8622
Device Common Name:	Continuous Ventilator, Facility Use
Device Classification Number:	21 CFR 868.5895
Device Classification & Product Code:	Class II, ONZ
Device Proprietary Name:	Ventilator (BT-V2S)

Predicate Device Information: [repeat table for each predicate]

Predicate Device:	BT-VS
Predicate Device Manufacturer:	Breathe Technologies Inc.
Predicate Device Common Name:	Continuous Ventilator, Facility Use
Predicate Device Premarket Notification #	K082982
Predicate Device Classification:	21 CFR 868.5895
Predicate Device Classification & Product Code:	Class II, ONZ

b. Date Summary Prepared
22 February 2010

c. Description of Device

c.1. Intended Patient Populations with Medical Condition

Breathe Technologies™ has identified a group of ventilator dependent, or highly oxygen dependent patients, in institutional settings that are being poorly served by standard ventilators excluding the predicate Breathe Technologies BT-VS. This group needs ventilation support but only at low levels. They need to ambulate within the facility and participate in respiratory, physical and occupational therapy. The ease of carrying the 1 pound ventilator, while their inspiratory efforts are properly supplemented, may allow for ambulation for these patients. It is intended only for institutional use.

c.2. General Description of the Breathe Technologies Ventilator and Patient Circuit (BT-V2S)

The Breathe Technologies™ Ventilator (BT-V2S) is a battery powered (which may be charged during use) wearable, volume ventilator that augments the patient's spontaneous breathing.

The BT-V2S administers this physician-prescribed volume to the patient via the attached Breathe Technologies Patient Circuit (BT-PC). The end of the BT-PC is inserted into the patient's tracheostomy tube.

The ventilator is small and light enough to be worn on a patient's belt, or slung over their shoulder.

d. Intended Use

The Breathe Technologies™ Ventilator BT-V2S, with accessories, is a volume assist ventilator intended to aid patients with respiratory insufficiency. It is designed for patients with a tracheostomy that 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 environment. The device is intended for operation by trained personnel under the direction of a physician

e. Comparison to Predicate Device
The BT-V2S is substantially equivalent in design, performance, software, materials, and intended use to the predicate device BT-VS, K#0802982 cleared July 20, 2009.

Both devices provide volume assist ventilation through a patient circuit inserted into a trans-tracheal tube to aid patients with respiratory insufficiency.

Both devices supply oxygen supplemented by entrained ambient air through the patient circuit.

Both devices are triggered by a patients' inspiration.

The **devices** use different mechanical components allowing for a lighter weight and smaller footprint. The predicate device weighs 3.1lbs while the subject device weighs 1lb. The Company device may be more appropriate for patients as it is easier and lighter when worn.

The testing described below demonstrates that the differences in the devices do not raise any unresolved issues of safety or efficacy.

Both ventilators may be cleaned using the same method and both patient circuits are single use only and ethylene oxide sterilized.

Company concludes that the devices are substantially equivalent.

f. Summary of Supporting Data
Biocompatibility data demonstrates that the device is in compliance with ISO 10993.

Bench testing has demonstrated that the device is in compliance with the medical community's expectations, the product labeling and pertinent sections of the guidance's and standards.

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

Ms. Suzon Lommel
Vice President, Regulatory and Quality Affairs
Breathe Technologies, Incorporated
4000 Executive Parkway, Suite 190
San Ramon, California 94583

APR 23 2010

Re: K100528
Trade/Device Name: Ventilator, BT-V2S with Accessories
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: ONZ
Dated: April 20, 2010
Received: April 21, 2010

Dear Ms. Lommel:

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 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 Inc. Ventilator, BT-V2S with accessories

The Breathe Technologies™ Ventilator BT-V2S, with accessories, is a volume assist ventilator intended to aid adult patients with respiratory insufficiency. It is designed for patients with a tracheostomy that 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 environment. The device is intended for operation by trained personnel 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)

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

510(k) Number: K100528