K082982

JUL 20 2009

Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor:	Breathe Technologies 3089 Skyway Court Fremont, CA 94539-5909 Tel: 510.360.9966 Fax: 510.360.9967
Correspondent Contact Information:	Suzon Lommel Breathe Technologies 4000 Executive Parkway Suite 190 San Ramon, CA 94583
Device Common Name:	Continuous Ventilator, Facility Use
Device Classification & Code:	Class II, CBK
Device Classification Name:	21 CFR 868.5895
Device Proprietary Name:	Ventilator

Predicate Device Information:

Predicate Device:	LTV 1000 & 800 Models
Predicate Device Manufacturer:	Pulmonetic Systems
Predicate Device Common Name:	Continuous Ventilator, Facility Use
Predicate Device Classification:	21 CFR 868.5895
Predicate Device Classification & Code:	Class II, CBK
Premarket Notification Number:	K981371

Predicate Device:	Legendair XL2
Predicate Device Manufacturer:	Puritan Bennett
Predicate Device Common Name:	Continuous Ventilator, Facility Use
Predicate Device Classification:	21 CFR 868.5895
Predicate Device Classification & Code:	Class II, CBK
Premarket Notification Number:	K070899

b. Date Summary Prepared

10 June 2009

c. Description of Device

c.1. Intended Patient Populations and Medical Conditions

Breathe Technologies has identified a group of ventilator dependent, or highly oxygen dependent patients, in institutional settings that are being poorly served by current ventilators. This group needs ventilation support but only at low levels. They need mobility within the facility. "Mobility" includes modest movement such as free motion in

bed, standing and sitting to use a commode, and movement to the bathroom. It may also, at the physicians' discretion, allow a level of ambulation to support participation in physical therapy, but the weight and bulk of current ventilators greatly inhibit their potential for physical movement. The ease of carrying the 3.1 lb ventilator, while their inspiratory efforts are properly supplemented, may allow the potential for ambulation for these patients. It is intended only for institutional use, not for home use.

c.2. General Description of the Breathe Technologies Ventilator, Transtracheal Tube and accessories

The Breathe Technologies™ Ventilator (BT-V) is a battery powered, wearable, volume ventilator that augments the patient's spontaneous breathing.

The BT-V administers this physician-prescribed volume to the patient via the attached Breathe Technologies Transtracheal Tube (BT-TT). The end of the BT-TT 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, because it has only a subset of the features of a full-featured ventilator.

d. Intended Use

The Breathe Technologies™ Ventilator (BT-V), 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 BT-V is designed for continuous applications in an institutional environment. The BT-V is a restricted medical device intended for operation by trained personnel under the direction of a physician.

e. Comparison to Predicate Device

The Breathe Technologies Ventilation System (Ventilator and Accessories) is substantially equivalent to the predicate Pulmonetic Systems' LTV 1000 & 800 Models (K981371) and the Puritan Bennett Legendair XL2 (K070899) in intended use, classification code, technology design and physician's use in that it conforms to a subset of the intended use, technology, physician use, features, performance and alarms of the predicate devices.

By conforming to a subset of design and use of the predicate devices, the Breathe Technologies Ventilation System can be used by some spontaneously breathing, ventilator dependent patients, to ambulate in an institutional setting.

Breath Technologies concludes that the predicate devices and the Breathe Technologies Ventilator System (Ventilator and all accessories) 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 the pertinent sections of the guidance's and standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 9 2009

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

Re: K082982
Trade/Device Name: Breathe Technologies Ventilator & Accessories
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: ONZ
Dated: June 25, 2009
Received: June 30, 2009

Dear Ms. Lommel:

This letter corrects our substantially equivalent letter of July 20, 2009.

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 (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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, DDS, MA
Acting Division 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 K082982:

Device Name: Breathe Technologies Ventilator & 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 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)

R [signature] Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K082982