K090113

510(k) SUMMARY

MAY 14 2009

Submitter	Breas Medical AB Foretagsvagen 1 SE 435 33 Molnlycke Sweden
Contact Person	Birgitta Bolander Quality & Regulatory Affairs Director Phone: +46 31 868830 Fax: +46 31 868810
Summary Date	2008-12-09
Name of Device	Breas Vivo 40 System
Common Name	Vivo 40 Target Volume
Classification Name	Non- continuous ventilator (21 CFR 868.5895)
Product Code	MNT
Predicate Devices	Breas Vivo 40 (current device (K071702) Respironics BiPAP® AVAPS (K070328)

Device Description:

The Vivo 40 is a pressure-supported and pressure-controlled ventilator with a CPAP function intended for spontaneously breathing patients to augment the breathing.

In the treatment of chronic respiratory failure, positive airway pressure ventilation is well established and common practice as a mean to assure sufficient gas exchange. There are a number of devices legally marketed in the United States for this application.

The therapy delivered by the Breas Vivo 40 System can be either:

1) Pressure Controlled Ventilation (PCV) or
2) Pressure Support Ventilation (PSV) or
3) Constant Positive Airway Pressure (CPAP)

The Vivo 40 airflow is delivered via a single lumen outlet tube that may be connected to various non-invasive and invasive patient interfaces, such as nasal masks. To minimize CO_2 rebreathing, masks or other interfaces permitting a leak flow of at least 12 liters/minute at the output pressure setting of 4 cmH_20 are recommended.

The Vivo 40 has an auto-switching power supply that facilitates use in conjunction with international travel (100 – 240 VAC). It can also be used with an external 12.5/ 24 VDC power source when AC mains line voltage is not available.

The outer dimensions of the Vivo 40 housing are 7.2 × 9.1 × 8.9 inches, and the device weighs 8.9 pounds.

Intended Use:

The Vivo 40 is an assist ventilator intended to augment the breathing of spontaneously breathing adult patients >66 lbs (>30 kg) suffering from respiratory failure, respiratory insufficiency, or obstructive sleep apnea.

The Vivo 40 is not intended to provide the total ventilatory requirements of the patient.

The Vivo 40 is intended to be used for both invasive and non-invasive applications.

The Vivo 40 is intended to be operated by qualified and trained personnel.

The Vivo 40 is intended for use in clinical settings (e.g., hospitals, sleep laboratories, sub-acute care institutions) and home environments.

The Vivo 40 must always be prescribed by a licensed physician.

Device modification
The modification is to add the feature Target Volume.

Comparison of Technological Characteristics

Compared to main predicate device Breas Vivo 40 (current version without Target Volume) the new device Breas Vivo 40 Target Volume has:

- Same Technology (software based pressure-, flow- and time- regulation)
- Same Design (microprocessor-controlled blower as air source)
- Same Environments of use
- Same Intended use

Compared to predicate device Respironics BiPAP AVAPS the new device Breas Vivo 40 Target Volume has

- Same Technology (software based pressure-, flow- and time- regulation)
- Same Target Volume Technology (Automatic pressure adjustments between the chosen IPAPmax and IPAPmin in order to reach and keep the desired tidal volume.
- Similar design (microprocessor-controlled blower as air source)
- Same environments of use
- Same Intended use (apart from Invasive use included for Breas Vivo 40 Target Volume)

Non-clinical performance data
To determine equivalence between the Breas Vivo 40 without Target Volume, Breas Vivo 40 Target Volume and Respironics BiPAP AVAPS bench testing was performed. This testing includes Pressure stability, Dynamic pressure regulation, Waveform performance and Target volume feature.

Conclusions drawn from the nonclinical tests
Bench testing has confirmed that the new device Breas Vivo 40 is substantial equivalent with regards to Wave-form performance as well as Work of Breathing, Pressure Dynamic regulation and Target Volume feature.

Clinical performance data
No clinical testing has been performed by Breas Medical.

Rather, one clinical article supporting the use of volume controlled ventilation in combination with pressure controlled has been attached. See appendix 12.

In conclusion, pressure controlled ventilation with Target Volume feature is as safe and effective as that of therapy without Target Volume feature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2009

Ms. Birgitta Bolander
Quality & Regulatory Affairs Director
Breas Medical AB
Foretagsvagen 1
SE 435 33 Molnlycke
SWEDEN

Re: K090113
Trade/Device Name: Breas Vivo 40 Target Volume
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNT
Dated: April 15, 2009
Received: April 22, 2009

Dear Ms. Bolander:

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.

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) 276-0120. 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, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Breas Vivo 40 Target Volume

Indications for Use:

The Vivo 40 is an assist ventilator intended to augment the breathing of spontaneously breathing adult patients >66 lbs (>30 kg) suffering from respiratory failure, respiratory insufficiency, or obstructive sleep apnea.

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The Vivo 40 is intended to be used for both invasive and non-invasive applications.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K90113