DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 9, 2016

Breas Medical AB
% Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, Massachusetts 01864

Re: K160481
Trade/Device Name: Vivo 60
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: NOU, CBK, DQA, CCK
Dated: October 12, 2016
Received: October 13, 2016

Dear Ms. O'Connell:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
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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 below.

510(k) Number *(if known)*
K160481

Device Name
Vivo 60

Indications for Use *(Describe)*
The Vivo 60 ventilator (with or without the iOxy and CO2 sensor) is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for pediatric through adult patients weighing more than 5 kg (11 lbs.)

The Vivo 60 with the iOxy is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate.

The Vivo 60 with the CO2 sensor is intended to measure CO2 in the inspiratory and expiratory gas.

The device is intended to be used in home, institution, hospitals and portable applications such as wheelchairs and gurneys. It may be used for both invasive and non-invasive ventilation. The Vivo 60 is not intended to be used as a transport or critical care ventilator.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

Prepared in accordance with 21 CFR § 807.92

Date Summary Prepared: November 8, 2016

Submitter Information:

Company Name: Breas Medical AB
Company Address: Företagsvagen 1
Mölnlycke Vastra Gotalands Lan (Se-14)
SWEDEN 435 33

Contact Person: Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Telephone: 978-207-1245

Device Information:

Trade Name: Vivo 60
Common Name: Portable Ventilator
Classification Name: Continuous Ventilator, Home Use
Product code: NOU
21 CFR §868.5895

Additional product codes:
Continuous Ventilators, Facility Use
Product code: CBK
21 C.F.R. §868.5895.

Oximeters
Product code: DQA
21 C.F.R. §870.2700.

Carbon Dioxide Gas Analyzer
Product code CCK
21 C.F.R. §868.1400.

Device Class: Class II

Predicate Devices:

Device:	Vivo 50
510(k) Number:	K123144
Manufacturer:	Breas Medical

Device:	Astral 110/150
510(k) Number:	K133868
Manufacturer:	ResMed Corporation

Intended Use:
To provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.

Indications for Use:
The Vivo 60 ventilator (with or without the iOxy and CO_2 sensor) is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for pediatric through adult patients weighing more than 5 kg (11 lbs.)

The Vivo 60 with the iOxy is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate.

The Vivo 60 with the CO_2 sensor is intended to measure CO_2 in the inspiratory and expiratory gas.

The device is intended to be used in home, institution, hospitals and portable applications such as wheelchairs and gurneys. It may be used for both invasive and non-invasive ventilation. The Vivo 60 is not intended to be used as a transport or critical care ventilator.

Device Description:
The Vivo 60 Ventilator is a portable, microprocessor controlled turbine based pressure support, pressure control or volume controlled ventilator intended for the care of individuals who require mechanical ventilation.

Flow and pressure are read through flow and pressure sensors. Essential parameters such as pressure, flow and volume are presented on the ventilator screen, both as graphs and numbers.

Operator actions are performed via the front panel where the buttons and an LCD screen are located. There are dedicated LEDs and buttons for managing alarm conditions and an Information button which provides integrated user support.

The Vivo 60 can be operated by external AC or DC power supply and contains an integrated battery as well as an additional click on battery.

The Vivo 60 can be used with three types of patient circuits: single limb patient circuits including an active exhalation valve, single limb patient circuits including a passive leakage port, and dual limb patient circuits.

Technological Characteristics Compared to Predicate:
The indications for use for the Vivo 60 and the Vivo 50 are identical with the exception that the Vivo 60 can be used in pediatric patients with a weight as low as 5 kg while the Vivo 50 is used in patients beginning at 10 kg. The Astral 100/150 has similar indications for use and can also be used in patients to 5 kg. All three of the devices are used in home,

institution and portable applications. Both the Vivo 60 and Vivo 50 are not to be used as a transport or critical care ventilator.

The Vivo 60, Vivo 50 and Astral ventilators have the same technological characteristics. All three are software controlled devices that receive ambient air through an inlet, utilize a turbine to generate the required pressures and flows, and pass the air to the patient via an outlet. All three devices provide a bleed-in connection for a low pressure, low flow supplemental oxygen supply. There are minor differences between the Vivo 60 and the Vivo 50 including: addition of compatibility with dual limb patient circuits**,** separate adult and pediatric patient types, addition of Synchronized Intermittent Mandatory Ventilation breath-mode ("SIMV"), and minor changes to performance specifications.

The Vivo 50, Vivo 60 and Astral ventilators can all be used with single limb with leak patient circuits, and single limb with active exhalation valve patient circuits. Additionally, the Vivo 60 and Astral can be used with dual limb patient circuits. The Vivo 60, Vivo 50, and Astral ventilators are for use by pediatric through adult patients. The Vivo 60 and the Astral have selectable "Pediatric" and "Adult" patient type settings. The Vivo 50 has a single fixed patient type setting to be used for both pediatric and adult patients. The selected patient type only determines the range of available settings (but does not alter the ventilation algorithms). The Vivo 60, Vivo 50 and Astral have nine ventilation modes in common, including pressure support ventilation (with and without target volume), pressure controlled ventilation (with and without target volume and/or assist), volume controlled ventilation (with or without assist), and CPAP. The ventilation algorithms utilized within these nine ventilation modes are identical between the Vivo 60 and Vivo 50. The Vivo 60 and Astral have two additional ventilation modes in common: pressure controlled ventilation with SIMV, and volume controlled ventilation with SIMV. These SIMV modes in the Vivo 60 utilize the same algorithms for delivering individual breaths as in the Vivo 50. In both the Vivo 60 and Astral, the SIMV modes are mixed ventilation modes delivering pressure-controlled or volume-controlled mandatory breaths, and pressure-supported spontaneous breaths.

The user interface, indicators and physical specifications are identical between the Vivo 60 and Vivo 50 as are power management and environmental characteristics.

Although there are differences between the Vivo 60 and the predicate devices, they do not impact safety and effectiveness. Therefore, the Vivo 60 is substantially equivalent to the Vivo 50 and Astral predicate devices.

Performance Testing:
The Vivo 60 was subjected to performance testing which verified conformance with all requirements specifications and applicable standards, and which included comparative testing with the Vivo 50 and Astral predicate devices which supported substantial equivalence. Performance testing included testing to the standards and procedures listed below:

Performance Testing to Standards	
Electrical Safety	IEC 60601-1: 2005+CORR. 1:2006+CORR.2: 2007+AM1:2012 Medical Electrical Equipment: General requirements for basic safety and essential performance
Electromagnetic compatibility	IEC 60601-1-2: 2014 (Ed. 4) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility
Alarms systems	IEC 60601-1-8: 2006 General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
Medical equipment used in home healthcare environment	IEC 60601-1-11: 2010 General requirements for basic safety and essential performance-Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Respiratory gas monitors	ISO 80601-2-55: 2011 (1st Ed) Medical electrical equipment-Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
Pulse oximeter equipment	ISO 80601-2-61:2011 (1st Ed) Medical electrical equipment-Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
Home healthcare environment ventilators for ventilator-dependent patients	ISO 80601-2-72:2015 (1st Ed) Medical electrical equipment-Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
Rough handling shocks	IEC 60068-2-31:2008 Environmental testing. Part 2-31: Tests – Rough handling shocks, primarily for equipment-type specimens. Drop and Topple test and Free Fall – procedure 1.
Battery testing	IEC 62133: 2012 (2nd Ed) Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
Biocompatibility	ISO 10993-1:2009 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process. Biocompatibility testing performed: • Cytotoxicity • Sensitization • Irritation/intracutaneous reactivity • Acute systemic toxicity • Pyrogenicity

	• Subacute/subchronic toxicity • Genotoxicity • Implantation • Hemocompatibility
VOC testing	Compendium Method TO-15 "Determination Of Volatile Organic Compounds (VOCs) In Air Collected In Specially-Prepared Canisters And Analyzed By Gas Chromatography/Mass Spectrometry (GC/MS)", U.S. EPA, and ASTM D5466-01 Standard test method for determination of volatile organic compounds in atmospheres (canister sampling methodology)
Particulates testing	EPA PM2.5 standard

Performance Testing
Waveform performance testing was conducted comparing the Vivo 60 to Vivo 50 and the Vivo 60 to the Astral. Characteristics tested included flow, pressure and volume waveforms. The comparison of the recorded waveforms supports the claim that Vivo 60 is substantially equivalent to the predicate devices.
Triggering testing of Vivo 60 was performed which showed that the Vivo 60 performed as intended, detecting each patient effort within the permissible trigger delay without false-triggers.
Testing of the Vivo 60 was performed to confirm accuracy of controls and monitored values. The testing confirmed that the Vivo 60 meets its accuracy specifications.
Alarms testing of the Vivo 60 was performed which confirmed proper operation of physiologic and technical alarms.
Power management testing confirmed proper operation of the Vivo 60 power management system including transitioning between the different internal and external power sources, power source alarms, and battery operating time.
Treatment and alarm settings testing confirmed the range and operation of settings for all treatment and alarm parameters conform to specifications.
Cybersecurity testing confirmed conformance with all cybersecurity specifications.
Software verification and validation were performed at the unit, integration, and system level according to plans and protocols with predetermined pass/fail criteria. All tests passed.
Summative usability / human factors testing was performed including critical tasks associated with the changes from the Vivo 50 to the Vivo 60.
Testing for immunity to emissions from RFID sources was conducted at 125kHz, 134.2kHz, 13.56MHz, 902MHz and using an Electronic Article Surveillance system.
Cleaning validation was performed to ensure no physical or performance degradation occurred.

Performance testing conducted with the Vivo 60 demonstrates compliance with recognized standards and product specifications. This testing including comparative

testing with the predicate devices supports use of the device for its intended use and in its intended environments.

Conclusion:
The Vivo 60 is substantially equivalent to the predicate devices, as the devices share a common intended use, and technological differences between the new devices and the predicates do not raise new questions of safety and effectiveness.