May 3, 2024

OConnell Regulatory Consultants, Inc.
Maureen OConnell
Regulatory Consultant
44 Oak Street
Stoneham, Massachusetts 02180

Re: K232365
Trade/Device Name: Vivo 45 LS
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK, NOU, DQA, CCK
Dated: April 7, 2024
Received: April 8, 2024

Dear Maureen OConnell:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and

Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K232365

Device Name
Vivo 45 LS

Indications for Use *(Describe)*
The Vivo 45 LS ventilator (with or without the SpO2 and CO2 sensors) 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.), however, the mouthpiece ventilation and Auto EPAP modes are only for adult patients during non-invasive ventilation.

The Vivo 45 LS with the SpO2 sensor is intended to measure functional oxygen saturation of arterial hemoglobin (% SpO2) and pulse rate.

The Vivo 45 LS 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 45 LS is not intended to be used as an emergency transport or critical care ventilator. The Auto EPAP feature is for use with PSV+TgV+AE mode in hospital use only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Breas Medical
Vivo 45 LS
K232365

510(k) Owner
Breas Medical AB
Foretagsvagen 1
Molnlycke, Vastra Gotalands Lan (Se-14)
SWEDEN 435 33

Submission Correspondent
Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, MA 02180
Phone: 978-207-1245

Date Prepared: May 1, 2024

Trade Names of Device
Vivo 45 LS

Common or Usual Name
Continuous ventilators, home use

Classification Name
Continuous ventilators, facility use;
21 C.F.R. §868.5895 Class II
Product Code: CBK

Additionally:
Continuous ventilators, home use;
Product Code: NOU

Oximeters;
Product Code: DQA

Carbon dioxide gas analyzer;
Product Code: CCK

Primary Predicate Device(s)
Breas Medical Vivo 45 LS cleared in K193586

Secondary Predicate Device(s)
Respironics Inc. Trilogy Evo cleared in K181166

Indications for Use
The Vivo 45 LS ventilator (with or without the SpO_2 and CO_2 sensors) 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.), however, the mouthpiece ventilation and Auto EPAP modes are only for adult patients during non-invasive ventilation.

The Vivo 45 LS with the SpO2 sensor is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate.

The Vivo 45 LS 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 45 LS is not intended to be used as an emergency transport or critical care ventilator. The Auto EPAP feature is for use with PSV+TgV+AE mode in hospital use only.

Device Description
The Vivo 45 LS 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 using flow and pressure sensors. Essential parameters such as pressure, flow and volume are presented on the ventilator screen, both in the form as graphs and numbers.

Operator actions are performed via the front panel where the buttons and an LCD screen are located (and two dedicated buttons on the top of the ventilator control starting/stopping treatment and pausing the alarm audio). There are dedicated LEDs and buttons for managing alarm conditions and an Information button which provides integrated user support.

The Vivo 45 LS can be operated by external AC or DC power supply and contains an integrated battery as well as an optional click in battery.

The Vivo 45 LS can be used with two types of patient circuits: single limb patient circuits including an active exhalation valve and single limb patient circuits including a passive leakage port.

Technological Characteristics Compared to Predicate
Breas Medical's Vivo 45 LS is a modification to Breas Medical's previously cleared Vivo 45 LS (K193586) which is the primary predicate device. The Trilogy Evo (K181166) is the secondary predicate device for the AutoEPAP mode and the flow trigger.

The Vivo 45 LS that is the subject of this 510(k) shares the same mechanical parts, electronics, and software as the Vivo 45 LS cleared in K193586, except for the differences described below.

Auto EPAP: The device software has been modified to provide an option for auto-titration of the Expiratory Positive Airway Pressure (EPAP) in pressure ventilation modes. Auto EPAP is indicated for adult patients during non-invasive ventilation with a passive leakage circuit. The Auto EPAP function adjusts the EPAP level within a clinician-prescribed range in response to detected changes in upper-airway resistance to maintain airway patency. The Auto EPAP feature is limited to the PSV+TgV+AE mode.

Flow Trigger: A flow-based inspiratory trigger option has been added. When passive leakage circuits are used, the user can select either the existing type of trigger available in the predicate device (tradename "eSync"), or the flow trigger. With the flow trigger selected, the user chooses the patient flow level in liters per minute to trigger a breath.

Both the Vivo 45 LS and the Trilogy Evo limit use of the function to non-invasive ventilation with passive leakage circuits in pressure ventilation modes only. Auto EPAP in the Trilogy Evo is intended for patients ≥ 10 kg, and in the Vivo 45 LS for Adult patient only (i.e., within the range of the Trilogy Evo). Both devices make the Auto EPAP function available in equivalent pressure ventilation modes as discussed above. The Auto EPAP functions of both devices monitor for changes in the estimated expiratory resistance of the upper airway and titrate the EPAP with the aim of finding the knee of the EPAP versus upper airway resistance curve (i.e., the EPAP above which there is no added benefit in terms of airway patency and below which the upper airway resistance progressively increases). Both devices provide the same set of Auto EPAP related settings including EPAP Min/Max, PS Min/Max, and Pressure Limit ("Max Pressure") to allow the prescribing clinician to constrain the EPAP and inspiratory pressure to remain within an acceptable range for the given patient. All of the alarms provided by the Trilogy Evo in AVAPS-AE mode are also provided by the Vivo 45 LS with Auto EPAP enabled.

The flow trigger of the subject device is equivalent to the flow trigger of the Trilogy Evo in terms of design (triggering when the estimated patient flow exceeds a user-specified threshold) and the user-selectable threshold ranges available. The flow triggers of both devices were utilized in comparative testing of the Auto EPAP function, which further supports equivalence.

The Breas Vivo 45 LS has the same intended use and similar technological characteristics to the predicate devices.

Performance Data
The Vivo 45 LS was subjected to performance testing related to the software modifications which verified conformance with all requirements specifications and applicable standards, and

which included comparative testing with the Vivo 45 LS predicate device which supported substantial equivalence. The Auto EPAP feature in PSV+TgV+AE mode uses an expiratory time constant measurement, or absence of flow measurement, as the input parameter to the Auto EPAP adjustment algorithm. The Auto EPAP feature in the PSV+TgV+AE mode was validated with a combination of real world patient data and simulated lung model bench testing. Real world patient data included a retrospective review of device data from 30 patients for safety analysis, and data from 30 patients regarding efficacy.

Performance Testing
Testing of flow trigger was performed which showed that the trigger performed as intended, detecting patient efforts as expected according to the user sensitivity setting across the intended range. Further verification testing of the flow trigger function demonstrated that it met all specifications.
Testing of the Vivo 45 LS was performed to confirm accuracy of controls and monitored values. The testing confirmed that the Vivo 45 LS meets its accuracy specifications.
Alarms testing of the Vivo 45 LS was performed which confirmed proper operation of physiologic and technical alarms.
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.

The testing described confirms that the Vivo 45 LS meets all requirements specifications and complies with the relevant standards, and is therefore substantially equivalent to the predicate devices.

Conclusion:
The Vivo 45 LS is substantially equivalent to the predicate devices, as the devices share a common intended use and technological characteristics as demonstrated through performance testing.