January 27, 2021

Breas Medical AB
% Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, Massachusetts 02180

Re: K193586
Trade/Device Name: Vivo 45 LS
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: NOU, CBK, DQA, CCK
Dated: December 23, 2020
Received: December 28, 2020

Dear Maureen 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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Brandon L. Blakely, Ph.D.
Acting Assistant Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193586

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 modes are for adult patients only.

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.

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: January 20, 2021

Submitter Information:

Company Name: Breas Medical AB
Company Address: Företagsvagen 1
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SWEDEN

Contact Person: Maureen O'Connell
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44 Oak Street
Stoneham, MA 02180
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Device Information:

Trade Name: Vivo 45 LS
Common Name: Portable Ventilator
Classification Name: Continuous Ventilator
Product code: NOU
21 CFR §868.5895

Additional product codes:
Continuous Ventilator
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 Device (Primary):	Device:	Vivo 60
	510(k) Number:	K160481
	Manufacturer:	Breas Medical
Predicate Device (Secondary):	Device:	Trilogy Evo
	510(k) Number:	K181166
	Manufacturer:	Respironics

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

Indications for Use:
The Vivo 45 LS ventilator (with or without the SpO2 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 modes are for adult patients only.

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.

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:
The Vivo 45 LS is a modification to the Vivo 60 ventilator cleared in K160481. The Vivo 45 LS is physically smaller than the Vivo 60 and includes some added features. The Vivo 45 LS user interface design is the same as the Vivo 60, with the same layout of displays, data and menus on the LCD screen, and the same layout of physical buttons for the user to take actions such as starting and stopping treatment, navigating the screen, and selecting parameters. The Vivo 45 LS software originated from the Vivo 60 software, and as such shares the same algorithms and remains very similar. The 45 LS electronics design also originated from the Vivo 60 and remains very similar. The blower inside the Vivo 45 LS is a slightly smaller version of the blower inside the Vivo 60 but has the same mechanical and electrical design.

The Breas Vivo 45 LS has the same intended use and similar technological characteristics to the two predicate devices; the primary predicate device is the Vivo 45 LS (cleared in K160481) and the secondary predicate is the Respironics Trilogy Evo (cleared in K181166). Breas Medical believes that the Vivo 45 LS described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to legally marketed predicate devices that are also Class II medical devices.

The intended use of the Vivo 45 LS it to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation which is the same as the intended use for the Vivo 60. Although the Vivo 45 LS is a modification of the Vivo 60 and has many shared features, there are also technological characteristics which are different. Both the Vivo 45 LS and the Vivo 60 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. Both devices provide a bleed-in connection for a low pressure, low flow supplemental oxygen supply. The majority of the ventilation modes are identical between the Vivo 45 LS and the Vivo 60 with one additional mode, mouthpiece ventilation, provided in the Vivo 45 LS. Additionally the ventilation parameter settings are largely unchanged as are the alarm settings. The accuracy of controls and accuracy of monitored values are the same between the devices. The user interfaces, power management features, environmental characteristics and data connectivity are all substantially equivalent between the devices. The optional accessories are either cleared in another 510(k) or substantially equivalent to those cleared in the predicate devices.

The Vivo 45 LS includes mouthpiece ventilation which is not included in the Vivo 60 but is a feature of the secondary predicate device, the Trilogy Evo. Both devices have the same intended use which is to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The Vivo 45 LS and the Trilogy Evo have the same technological characteristics in regards to mouthpiece ventilation with minor differences in the exact performance specifications.

The Vivo 45 LS is substantially equivalent to the combination of the Vivo 60 and Trilogy Evo both of which are legally marketed predicate devices.

Performance Testing:
The Vivo 45 LS was subjected to performance testing which verified conformance with all requirements specifications and applicable standards, and which included comparative testing with the Vivo 60 predicate device which supported substantial equivalence. Additional testing was performed to support the substantial equivalence to the secondary predicate device, the Trilogy Evo for the mouthpiece ventilation.

Performance testing included testing to the standards and procedures listed below:

Performance Testing to Standards	
Electrical Safety	ANSI/AAMI ES60601-1:2005 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
Electromagnetic compatibility	IEC 60601-1-2: 2014 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic disturbances-Requirements and tests
Usability	IEC 60601-1-6: 2010+A1:2013 Medical electrical equipment-Part

	1-6: General requirements for basic safety and essential performance-Collateral standard: Usability
Alarms systems	IEC 60601-1-8: 2006 (Second edition) + Am. 1: 2012 Medical electrical equipment-Part 1-8: 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: 2015 Medical electrical equipment-Part 1-11: General requirements for basic safety and essential performance-Collateral standard: Requirements for medical electrical equipment systems used in the home healthcare environment
Critical care ventilators	ISO 80601-2-12:2011 Medical electrical equipment Part 2-12: Particular requirements for safety of lung ventilators-Critical care ventilators
Respiratory gas monitors	ISO 80601-2-55: 2018 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of respiratory gas monitors
Pulse oximeter equipment	ISO 80601-2-61:2017 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 Medical electrical equipment Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
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: The materials which are in the gas pathway have been evaluated via gas emission VOC, inorganic gases (CO, CO2, and Ozone) and PM2.5/PM10 testing with a risk based assessment. The materials were found to be biocompatible for the intended use, intended population and type of patient contact. Further details are provided below which support substantial equivalence.	
VOC testing	ISO 18562-3: 2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications-Part 3: Tests for emissions of volatile organic compounds. No VOC compounds were observed in quantities that represent a toxicological risk to the intended patient population.
Particulates testing	ISO 18562-2: 2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications-Part 2: Tests for emissions of particulate matter. Particulate quantities were well below acceptable limits of exposure for all patient populations.
Carbon monoxide testing	The Vivo 45 LS was tested for generation of inorganic gases including carbon monoxide per the recommendations of ISO 18562-1. The Vivo 45 LS was found not to generate carbon monoxide.
Carbon dioxide testing	The Vivo 45 LS was tested for generation of inorganic gases including carbon dioxide per the recommendations of ISO 18562-1. The Vivo 45 LS was found not to generate carbon dioxide.
Ozone testing	The Vivo 45 LS was tested for generation of inorganic gases

	including ozone per the recommendations of ISO 18562-1. The Vivo 45 LS was found not to generate ozone.

Performance Testing
Waveform performance testing was conducted comparing the Vivo 45 LS to Vivo 60 (and to the Trilogy EVO for MPV modes). Characteristics tested included flow, pressure and volume waveforms. The comparison of the recorded waveforms supports the claim that Vivo 45 LS is substantially equivalent to the predicate devices.
Triggering testing of Vivo 45 LS was performed which showed that the Vivo 45 LS performed as intended, detecting each patient effort within the permissible trigger delay without false-triggers.
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.
Testing of the mouthpiece ventilation (MPV) and synchronized intermittent mandatory ventilation (SIMV) modes was performed and the Vivo 45 LS passed all tests.
Alarms testing of the Vivo 45 LS was performed which confirmed proper operation of physiologic and technical alarms.
Power management testing confirmed proper operation of the Vivo 45 LS 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 respiratory therapists, registered nurses, and lay caregivers, and the Vivo 45 LS was found to be safe and effective for the intended users, uses and use environments.
Cleaning validation was performed to ensure no physical or performance degradation occurred.
RFID immunity testing was performed to the Association for Automatic Identification and Mobility (AIM) standard 7351731includng 134 kHz and 13.56 MHz RFID sources. The Vivo 45 LS passed all tests.

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.