January 13, 2025

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

Re: K233452
Trade/Device Name: Vivo 45 LS
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, NOU, BTT, CCK, DQA
Dated: December 20, 2024
Received: December 20, 2024

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Anesthesia,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233452

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-K233452

Breas Medical
Vivo 45 LS

510(k) Owner
Breas Medical AB
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Submission Correspondent
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Date Prepared: January 9, 2025

Trade Names of Device
Vivo 45 LS

Common or Usual Name
Continuous ventilators, home use

Classification Name
Continuous ventilators; 21 C.F.R. §868.5895
Class II
Product Code: NOU

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

Reference Device(s)
Fisher & Paykel Healthcare, LTD. MR810Respiratory Humidifier cleared in K131957
Newport Medical Instruments, Inc. Newport HTS50 Ventilator With Dual Pac Battery System cleared in K082724
Fisher & Paykel Healthcare, LTD. myAIRVO 2 Humidifier cleared in K131895

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 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.

The Vivo 45 LS can be operated in the following combinations of ventilation and breath modes:

- PSV-Pressure Support Ventilation
- PSV(TgV)-Pressure Support Ventilation with Target Volume
- PCV-Pressure Controlled Ventilation
- PCV(TgV)-Pressure Controlled Ventilation with Target Volume
- PCV(A)-Assisted Pressure Controlled Ventilation
- PCV(A+TgV)-Assisted Pressure Controlled Ventilation with Target Volume
- PCV-SIMV-Pressure Controlled Ventilation with Synchronized Intermittent Mandatory Ventilation
- PCV-MPV-Pressure Controlled Ventilation with MouthPiece Ventilation
- VCV-Volume Controlled Ventilation
- VCV(A)-Assisted Volume Controlled Ventilation
- VCV-SIMV-Volume Controlled Ventilation with Synchronized Intermittent Mandatory Ventilation

- VCV-MPV- Volume Controlled Ventilation with MouthPiece Ventilation
- CPAP-Continuous Positive Airway Pressure, with optional features for HFNT-High Flow Nasal Therapy

High flow nasal therapy (HFNT) may be prescribed for spontaneously breathing patients undergoing non-invasive ventilatory therapy using a small, medium or large nasal cannula interface. The user may prescribe a flow rate setting in the range of 4 to 60 liters per minute. It is recommended to use an external humidifier, the Fisher & Paykel MR 850, during HFNT, due to possibly higher humidification output requirements of the patient. The Vivo 45 LS automatically disables the internal humidifier when the HFNT feature is being used.

Conditioning of the breathing air's temperature and humidity level may be prescribed for non-invasively ventilated patients using the integrated humidifier and heated wire patient circuit of the Vivo 45 LS at the clinician's discretion to enhance patient comfort and compliance. The humidification function is enabled by the Vivo 45 LS only when the device is powered by AC Mains and is automatically disabled including power to the heating plate when the device is powered by battery. The humidifier heating level can be selected by the user by setting the heating level (1-5) on the device user interface.

The Vivo 45 LS provides the user with available settings that determine the power delivered to the heater wire. This setting is in terms of a patient-end temperature in the range of 16 to 30° C. The heated wire patient circuit contains a temperature sensor located at the patient connection port, and the firmware of the Vivo 45 LS continuously monitors the temperature and automatically adjusts the power delivered to the heater wire to maintain the temperature at the user set point.

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. Three reference devices were used to support substantial equivalence of the humidifier and heated wire breathing circuit. Specifically, the Newport HTS50 Ventilator cleared in K082724 was used as a reference device to support an integrated humidifier, the MR810Respiratory Humidifier cleared in K131957 was used to support the humidifier and heated breathing circuit, and the myAIRVO 2 Humidifier cleared in K131895 was used to support substantial equivalence of the High Flow Humidification (HFNT).

The Breas Vivo 45 LS has the same intended use and similar technological characteristics to the predicate and reference devices. 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 and reference devices that are also Class II medical devices. Table 1 compares the Vivo 45 LS with the primary predicate Vivo 45 LS.

Table 1
Substantial Equivalence; Vivo 45 LS
Primary Predicate Device

Manufacturer	**Breas Medical AB**	**Breas Medical AB**	**Discussion of Differences**
Model	Vivo 45 LS (subject device)	Vivo 45 LS (predicate device)	-
510(k) Number	-	K193586	-
Software Controlled	Yes	Yes	Same
Gas Delivery System	Turbine	Turbine	Same
Air	Ambient air	Ambient air	Same
Oxygen Supply	Connection for low O2 pressure supply with bleed rate of 30 l/min	Connection for low O2 pressure supply with bleed rate of 15 l/min	Substantially equivalent: The design of the Vivo 45 LS remains unchanged. The oxygen flow is provided and controlled by an external oxygen supply.
Patient Type Settings	Adult - Invasive, Adult – NIV, Pediatric – Invasive, Pediatric – NIV	Adult, Pediatric	Substantially equivalent: Both devices provide Adult and Pediatric settings and both devices are indicated for invasive and non-invasive (NIV) ventilation.
Patient Circuit Types	Single Limb with Leak, Single Limb with Active Exhalation Valve	Single Limb with Leak, Single Limb with Active Exhalation Valve	Same
Circuit Compensation	Yes, Pre-use test	Yes, Pre-use test	Same

Manufacturer	Breas Medical AB	Breas Medical AB	Discussion of Differences
Model	Vivo 45 LS (subject device)	Vivo 45 LS (predicate device)	-
Ventilation Modes			
PSV, PSV(TgV)	Yes	Yes	Same
PCV, PCV(TgV), PCV(A), PCV(A+TgV), PCV-SIMV, PCV-MPV	Yes	Yes	Same
VCV, VCV(A), VCV-SIMV, VCV-MPV	Yes	Yes	Same
CPAP with optional features for HFNT	Yes	CPAP only	Substantially equivalent: High flow mode is analogous to CPAP mode except instead of a fixed pressure, the flow is fixed at the user-specified setting.

Ventilation Parameter Settings			
Inspiratory Pressure	Adult: 4 – 50 cmH2O Pediatric: 4 – 50 cmH2O (Limited to 30 cmH2O above PEEP)	Adult: 4 – 50 cmH2O Pediatric: 4 – 50 cmH2O (Limited to 30 cmH2O above PEEP)	Same
CPAP Pressure	4 to 20 cmH2O	4 to 20 cmH2O	Same
PEEP	0 to 20 cmH2O (circuit with exhalation valve) 2 to 20 cmH2O (circuit with leakage port)	0 to 20 cmH2O (circuit with exhalation valve) 2 to 20 cmH2O (circuit with leakage port)	Same
Breath Rate	4 to 40 BPM (Adult) 6 to 60 BPM (Pediatric)	4 to 40 BPM (Adult) 6 to 60 BPM (Pediatric)	Same
Inspiratory Time	0.3 to 5 sec (Adult) 0.3 to 2 sec (Pediatric)	0.3 to 5 sec (Adult) 0.3 to 2 sec (Pediatric)	Same
Trigger Type	eSync (circuit with exhalation valve) eSync (circuit with leakage port)	eSync (circuit with exhalation valve) eSync (circuit with leakage port)	Same

Manufacturer	Breas Medical AB	Breas Medical AB	Discussion of Differences
Model	**Vivo 45 LS (subject device)**	**Vivo 45 LS (predicate device)**	**-**
Rise Time	Rise Time – Pressure: 1 to 9 (PSV & PCV, PCV-SIMV, VCV-SIMV, PCV-MPV) Rise Time – Volume: 50% to 90% of insp. time, Off (VCV, VCV-SIMV, VCV-MPV)	Rise Time – Pressure: 1 to 9 (PSV & PCV, PCV-SIMV, VCV-SIMV, PCV-MPV) Rise Time – Volume: 50% to 90% of insp. time, Off (VCV, VCV-SIMV, VCV-MPV)	Same
Tidal Volume	300 to 2000 ml (Adult) 50 to 400 ml (Pediatric)	300 to 2000 ml (Adult) 50 to 400 ml (Pediatric)	Same
Sigh	Off, every 10 to 250 breaths (sigh interval) 125% to 200% of actual set pressure or volume within pressure/volume limits	Off, every 10 to 250 breaths (sigh interval) 125% to 200% of actual set pressure or volume within pressure/volume limits	Same
Flow Pattern	Square, Decelerating	Square, Decelerating	Same

Alarm Settings Note that the subject device includes HFNT. When HFNT is used, only the Disconnection, Obstruction, High/Low FiO2 and High/Low SpO2 alarms are available. This is consistent with other HFNT devices. The information presented below applies to all other ventilation modes.			
Low Pressure Alarm	Pediatric: 1 to 50 cmH2O Adult: 1 to 50 cmH2O	Pediatric: 1 to 50 cmH2O Adult: 1 to 50 cmH2O	Same
High Pressure Alarm	5 to 70 cmH2O	5 to 70 cmH2O	Same
Low Vt Alarm	Off, 100 to 2000 ml (Adult) Off, 20 to 500 ml (Pediatric)	Off, 100 to 2000 ml (Adult) Off, 20 to 500 ml (Pediatric)	Same

Manufacturer	Breas Medical AB	Breas Medical AB	Discussion of Differences
Model	Vivo 45 LS (subject device)	Vivo 45 LS (predicate device)	-
Low Minute Volume Alarm	Off, 1 to 30 liters (Adult) Off, 0.1 to 10 liters (Pediatric)	Off, 1 to 30 liters (Adult) Off, 0.1 to 10 liters (Pediatric)	Same
High Minute Volume Alarm	1 to 40 liters, Off (Adult) 1 to 20 liters, Off (Pediatric)	1 to 40 liters, Off (Adult) 1 to 20 liters, Off (Pediatric)	Same
Low PEEP Alarm	On, Off	On, Off	Same
High PEEP Alarm	On, Off	On, Off	Same
Disconnection (high leakage) Alarm	On, Off	On, Off	Same
Obstruction Alarm	On, Off	On, Off	Same
Low Breath Rate Alarm	Off, 4 to 30 BPM (Adult) Off, 1 to 30 BPM (Adult – MPV) Off, 6 to 50 BPM (Pediatric)	Off, 4 to 30 BPM (Adult) Off, 1 to 30 BPM (Adult – MPV) Off, 6 to 50 BPM (Pediatric)	Same
High Breath Rate Alarm	10 to 70 BPM, Off (Adult) 10 to 99 BPM, Off (Pediatric)	10 to 70 BPM, Off (Adult) 10 to 99 BPM, Off (Pediatric)	Same
Low Pulse Rate Alarm	Off, 30 to 230	Off, 20 to 250	Substantially equivalent: The subject device is within the specification of the predicate and within the accurate pulse rate reporting range of the pulse oximeter.
High Pulse Rate Alarm	30 to 230, Off	20 to 250, Off	Substantially equivalent: The subject device is within the specification of the predicate and within the accurate pulse rate reporting range of the pulse oximeter.
Low FiO2 Alarm	Off, 21 to 100%	Off, 21 to 100%	Same
High FiO2 Alarm	21 to 100%, Off	21 to 100%, Off	Same
Low SpO2 Alarm	Off, 85 to 100%	Off, 85 to 100%	Same

Manufacturer	Breas Medical AB	Breas Medical AB	Discussion of Differences
Model	Vivo 45 LS (subject device)	Vivo 45 LS (predicate device)	-
Low EtCO2 Alarm	Off, 1 to 99 mmHg	Off, 1 to 99 mmHg	Same
High EtCO2 Alarm	1 to 99 mmHg, Off	1 to 99 mmHg, Off	Same
High Insp CO2 Alarm	1 to 99 mmHg, Off	1 to 99 mmHg, Off	Same
Re-Breathing (low leakage) Alarm	On, Off	On, Off	Same
High Patient Air Temp Alarm	Yes	Yes	Same
Low Last Power Source Alarm	Yes	Yes	Same
Power Fail Alarm	Yes	Yes	Same
Low Alarm Battery Alarm	Yes	Yes	Same
Function Failure Alarms	Yes	Yes	Same
Alarm Pre-Silence	Yes	No	Substantially equivalent: Both devices share the same physical buttons, including the Audio Pause button which mutes active alarms in both devices. The subject device includes the additional alarm pre-silence function (pre-silencing of alarms for the coming 2 minutes). The existing Audio Pause hardware button is used for the pre-silence function by the user pressing and holding it down for three seconds. The pre-silence function is recommended in IEC 60601-1-8 Edition 2.1 Annex A Subclause 681 (FDA recognition number 5-76).

Manufacturer	Breas Medical AB	Breas Medical AB	Discussion of Differences
Model	Vivo 45 LS (subject device)	Vivo 45 LS (predicate device)	-
Accuracy of Controls			
Inspiratory Pressure	max of ±0.5cmH2O, ±5%	max of ±0.5cmH2O, ±5%	Same
PEEP	max of ±0.5cmH2O, ±5%	max of ±0.5cmH2O, ±5%	Same
Tidal Volume	max of ±12ml, ±10%	max of ±12ml, ±10%	Same
Breath Rate	±2%	±2%	Same
Inspiratory Time	Minimum of: ±(20 msec + 5% of setting), and ±0.1sec	Minimum of: ±(20 msec + 5% of setting), and ±0.1sec	Same
Accuracy of Monitored Values			
Ppeak	max of ±0.5cmH2O, ±10%	max of ±0.5cmH2O, ±10%	Same
PEEP	max of ±0.5cmH2O, ±10%	max of ±0.5cmH2O, ±10%	Same
Pmean	max of ±0.5cmH2O, ±10%	max of ±0.5cmH2O, ±10%	Same
Leakage	±10%	±10%	Same
Tidal Volume	max of ±10ml, ±10%	max of ±10ml, ±10%	Same
FiO2	±2%	±2%	Same
% in TgV	±1%	±1%	Same
Total Rate	±1bpm	±1bpm	Same
Spont Rate	±1bpm	±1bpm	Same
SpO2	±2%	±2%	Same
Pulse Rate	±1%	±1%	Same
I:E	±0.1 unit	±0.1 unit	Same

Manufacturer	Breas Medical AB	Breas Medical AB	Discussion of Differences
Model	Vivo 45 LS (subject device)	Vivo 45 LS (predicate device)	-
Rise Time	Max of ±10%, 0.1 sec	Max of ±10%, 0.1 sec	Same
EtCO2	±(0.3 vol% + 4% of reading) within 0-15% range	±(0.3 vol% + 4% of reading) within 0-15% range	Same
InspCO2	±(0.3 vol% + 4% of reading) within 0-15% range	±(0.3 vol% + 4% of reading) within 0-15% range	Same
Apnea-Hypopnea Index (AHI)	No	No	Same

The Vivo 45 LS is a modification to the Vivo 45 LS ventilator cleared in K193586. The devices share the same mechanical parts, electronics, and software, except for the differences described below.

High Flow Nasal Therapy (HFNT): The device software has been modified to provide an option for high flow nasal therapy in which the airflow is controlled according to a user setting.

Alarm Pre-Silence: The device software has been modified to provide the user the ability to pre-silence alarms for the coming two minutes. The existing Audio Pause hardware button for silencing active alarms is used for the pre-silence function by the user pressing and holding it down for three seconds.

Humidifier: Humidification can now be provided via a metal heater plate and associated electronics integrated into the base of the Vivo 45 LS device, combined with a click-in humidifier water chamber accessory which also has a metal plate that contacts the heater and transfers the heat to the water. The device software allows the user to set the heater temperature, controls the temperature, monitors for faults, and provides associated alarms. Use of the humidifier is limited to non-invasive ventilation only.

Heated Wire Patient Circuit: Heating of the patient circuit can now be provided via electronics integrated into the Vivo 45 LS device, combined with a heated wire patient circuit accessory which has a proprietary electrical connector that plugs into the back of the Vivo 45 LS device. The patient circuit accessory has a spiraled wire embedded in its wall to receive power the Vivo 45 LS and heat the wall, and a temperature sensor at the patient-end. The device software allows the user to set the temperature at the patient-end, controls the temperature, monitors for faults, and provides associated alarms. Use of the heated wire patient circuit is limited to non-invasive ventilation only.

Supplemental Oxygen Flow Rating: The rating for the maximum flow rate of oxygen introduced through the connector at the back of the Vivo 45 LS has been increased from 15 to 30 liters per minute. No changes to the Vivo 45 LS hardware or software were necessary to accommodate this change in rating. The change was made based on safety and performance

verification. The extended supplemental oxygen flow range can be useful for HFNT. The labeling of the Vivo 45 LS has been updated accordingly.

Performance Data

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 45 LS predicate device which supported substantial equivalence.

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 80601-2-12:2020 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 2-55: 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 IEC 62133-2 Edition 1.0 2017 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 – Part 2: Lithium systems
Humidifier testing	ISO 80601-2-74: 2017 Medical electrical equipment Part 2-74 : Particular requirements for basic safety and essential performance of respiratory humidifying equipment
Biocompatibility: The entire gas pathway including the Vivo 45 LS device, humidifier and heated wire patient circuit have been evaluated for emission of volatile organic compounds (VOC), inorganic gases (CO, CO2, and Ozone) and particulate matter (PM2.5/PM10) in accordance with ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process. The humidified gas pathway comprised of the humidifier water chamber and heated wire patient circuit have been evaluated for solvent-extractable compounds and biocompatibility in accordance with ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. Additionally, the device was evaluated for emissions of aldehydes. The Vivo 45 LS device and accessories 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	The entire gas pathway including the Vivo 45 LS device, humidifier and heated wire patient circuit have been tested in accordance with 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.
Particulate matter	The entire gas pathway including the Vivo 45 LS device, humidifier and heated wire patient circuit have been tested in accordance with 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	The entire gas pathway including the Vivo 45 LS device, humidifier and heated wire patient circuit have been tested for generation of inorganic gases including carbon monoxide per the recommendations of ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in

	healthcare applications - Part 1: Evaluation and testing within a risk management process. Carbon monoxide emission was well below acceptable limits of exposure for all patient populations.
Carbon dioxide	The entire gas pathway including the Vivo 45 LS device, humidifier and heated wire patient circuit have been tested for generation of inorganic gases including carbon dioxide per the recommendations of ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process. Carbon dioxide emission was well below acceptable limits of exposure for all patient populations.
Ozone	The entire gas pathway including the Vivo 45 LS device, humidifier and heated wire patient circuit have been tested for generation of inorganic gases including ozone per the recommendations of ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process. Ozone emission was well below acceptable limits of exposure for all patient populations.
Aldehydes	Aldehyde testing was conducted using the final, finished Vivo 45 LS device (newly manufactured). Sampling for emission of aldehydes from the device at multiple time-points was conducted within a heated chamber at approximately 40° C, with the device set to the minimal clinically relevant flow rate (i.e., worst-case conditions). Targeted analysis for Formaldehyde, Acetaldehyde, Acrolein, Propionaldehyde, Crotonaldehyde, Butyraldehyde, Benzaldehyde, Isovaleraldehyde, Valeraldehyde, Total-Tolualdehyde, Hexaldehyde, and 2,5-dimethylbenzaldehyde was performed. The conclusion was that the Vivo 45 LS does not pose a risk for aldehyde exposure to adult or pediatric subjects when operated under worst case temperature and flow rate conditions.
Extractable compounds	The humidified gas pathway comprised of the humidifier water chamber and heated wire patient circuit has been tested for extractable compounds per the recommendations in ISO 18562-4:2017 and ISO 10993-18:2020 Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process, with the conclusion that use of the Vivo 45 LS in adult subjects will not pose a significant toxicological or biocompatibility risk.
Cytotoxicity	The humidified gas pathway comprised of the humidifier

	water chamber and heated wire patient circuit has been tested for cytotoxicity in accordance with ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity. The test article was found to be non-cytotoxic.
Sensitization	The humidified gas pathway comprised of the humidifier water chamber and heated wire patient circuit has been tested for sensitization in accordance with ISO 10993-10:2010, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization. The test article was found to be non-sensitizing.
Irritation / Intracutaneous Reactivity	The humidified gas pathway comprised of the humidifier water chamber and heated wire patient circuit has been tested for irritation / intracutaneous reactivity in accordance with ISO 10993-10:2010, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization.. The test article was found to be non-irritating.
Acute Systemic Toxicity	The humidified gas pathway comprised of the humidifier water chamber and heated wire patient circuit has been tested for acute systemic toxicity in accordance with ISO 10993-11:2017 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity. The test article was found to be non-toxic.
Materials Mediated Pyrogenicity	The humidified gas pathway comprised of the humidifier water chamber and heated wire patient circuit has been tested for materials mediated pyrogenicity in accordance with ISO 10993-11:2017 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity. The test article was found to be non-pyrogenic.
Genotoxicity – Reverse Mutation	The humidified gas pathway comprised of the humidifier water chamber and heated wire patient circuit has been tested for genotoxicity reverse mutation in accordance with ISO 10993-3:2014, Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity. The test article was found to be non-mutagenic.

Performance Testing
Verification testing of the HFNT function was conducted, demonstrating that the function met all specifications.
Verification testing of the alarm pre-silence function was conducted, demonstrating that the function met all specifications.
The humidifier and heated wire functions were tested for humidity output, normal operation functions, detection and response to fault conditions including safe power cutoff and alarms, maximum water temperature, heated circuit temperature accuracy, cleaning, and gas leakage. Further, the Vivo 45 LS with these accessories installed

was subjected to comparative pressure, flow and volume waveforms testing versus the cleared Vivo 45 LS device. The Vivo 45 LS with humidifier and heated wire patient circuit met all specifications, and the comparative waveforms testing demonstrated equivalence to the cleared Vivo 45 LS device.
The Vivo 45 LS was tested with supplemental oxygen for safety and performance at the rated flow rate of 30 liters per minute. All tests passed.
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.
Summative human factors testing was performed which determined the Vivo 45 LS is safe and effective for the intended users, uses and use environments. The study included 15 healthcare professionals (HCP) who are respiratory therapists (RT) and 15 HCP who are registered nurses (RN) performing the tasks necessary to use the device in a clinical setting and 15 lay caregiver (LCG) users performing the tasks necessary to use the device in a home setting. The critical tasks for Vivo 45 LS use were tested with the intended users, for its intended use and in a representative use environment. Based on the performance of the test participants, their observed behaviors, subjective feedback, and a root cause analysis of all use errors, close calls and difficulties observed, use of the Vivo 45 LS was successfully validated. • The intended user populations can safely and successfully use the Vivo 45 LS • The training was understood and successfully applied by the users • Performance of critical tasks did not result in any patterns of use errors or difficulties that would lead to patient harm (including compromised medical care) • No new hazards, hazardous situations, or hazard-related use-scenarios were identified in the study • Use-related hazards have been reasonably mitigated and residual risks that cannot be further mitigated have been reduced as far as possible and are considered acceptable. In addition to the summative human factors study, the following HFE/UE processes have been conducted and support the conclusion regarding safety and efficacy: • Multiple formative HF studies

- Prior summative HF studies (and the present changes follow the same user interface paradigm as previously studied)
- Design reviews with subject matter experts
- Assessment of known use problems and review of field data
- Use-related risk management activities
- Discussion of residual use-related risk

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.