August 27, 2025

Nanjing Yinuoji Medical Technology Co., Ltd.
℅ Jerry Sudduth
QA/RA Consultant
Imangel Consulting, Inc.
Contact Address

Re: K250625
Trade/Device Name: Portable oxygen concentrator (W-R1(MAX)); Portable oxygen concentrator (W-R1); Portable oxygen concentrator (W-R2); Portable oxygen concentrator (W-R2(Lite))
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: July 21, 2025
Received: July 22, 2025

Dear Jerry Sudduth:

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250625

Device Name

Portable oxygen concentrator (W-R1(MAX));
Portable oxygen concentrator (W-R1);
Portable oxygen concentrator (W-R2);
Portable oxygen concentrator (W-R2(Lite))

Indications for Use *(Describe)*

The Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to adult patients requiring respiratory therapy on a prescriptive basis. It may be used at home, in institution, vehicle, train, airplane, boats and other transport modalities. This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.
Users should follow their doctor's advice on setting the oxygen flow rate and should not adjust the flow rate without consulting a healthcare professional.
Note: Patients should regularly consult with their physician to evaluate the need for adjustments in their oxygen therapy settings.

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.

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"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
Date Prepared: July 18, 2025

I. Submission Information:

Sponsor: Nanjing Yinuoji Medical Technology Co., Ltd.
Room 207, 2nd floor, Building B, No.95 Xingangwan Road, Longchi street, Luhe District, Nanjing , Jiangsu, China.

Sponsor Contact: Xiao Xu
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Submission Correspondent:
Imangel Consulting Inc.
Jerry Sudduth
jerry33782@yahoo.com
954-729-1411

II. Device information

Trade Name: Portable oxygen concentrator
Model(s): W-R1(MAX), W-R1, W-R2, W-R2(Lite)
Classification: II
Product Code: CAW
Regulation Number: 21 CFR 868.5440

III. Predicate Device:

Trade Name: Inogen Rove 6 Portable Oxygen Concentrator
Classification: II
Product Code: CAW
Regulation Number: 21 CFR 868.5440
510k number： K230052

IV. Reference device

Trade Name: GCE Zen-O Portable Oxygen Concentrator Model RS-00500
Classification: II
Product Code: CAW
Regulation Number: 21 CFR 868.5440
510k number： K162433

V. Device Description:

Image of the Portable Oxygen Concentrator

The Portable Oxygen Concentrator is a Class II, low-risk medical device designed to provide a high-concentration oxygen supply (87%-95.5%) to adult patients requiring supplemental oxygen therapy as prescribed by a healthcare professional. It is intended for use at home, in institution, vehicle, train, airplane, boats and other transport modalities and complies with FAA regulations for in-flight use. The device is not intended for life-support or life-sustaining purposes.

The Portable Oxygen Concentrator utilizes Pressure Swing Adsorption (PSA) technology, which extracts oxygen from ambient air by selectively adsorbing nitrogen through molecular sieve beds. Oxygen is delivered through a pulse dose mechanism, synchronizing oxygen release with the patient's inhalation cycle to optimize efficiency and minimize waste. The series consists of four models, each offering different pulse dose settings:W-R1 (MAX): 1, 2, 3, 4, 5, 6, S/W-R1: 1, 2, 3, 4, 5, 6/W-R2: 1, 2, 3, 4, 5/W-R2 (Lite): 1, 2, 3, 4.

The device operates in pulse flow mode and supports multiple power sources, including 100–240V AC (50–60Hz) and a rechargeable lithium-ion battery (14.4V / 6500mAh). While the hardware supports 13.0–16.8V DC input, DC operation is not currently supported, as no DC accessories are provided or authorized. A single battery charge provides up to 4.5 hours of continuous use, ensuring flexibility across various environments.

Designed for portability and efficiency, the W-R Series features a lightweight build (1.8 kg), low noise operatio, and an intuitive LCD display. Its ergonomic and user-friendly design has been internationally recognized with six global design awards, including iF, Red Dot, and IDEA, for its usability, portability, and patient-centered innovation.

The device is suitable for operation within a temperature range of -5°C to 40°C (23°F to 104°F), humidity levels of 5% to 90% (non-condensing), and atmospheric pressure from 54kPa to 106kPa. It can function at altitudes up to 5,000 meters (16,400 feet).

The Portable Oxygen Concentrator consists of a casing, compressor, molecular sieve system, solenoid valve, battery, cooling fan, control board, and display screen.

Note: The device does not include a nasal cannula; patients should purchase one

separately. The oxygen outlet follows international standards, and recommended cannula specifications can be found in Section 2.12: Cannula Use of the user manual.

Specifications

Manufacturer	Nanjing Yinuoji Medical Technology Co., Ltd.			
Model	W-R1（MAX）	W-R1	W-R2	W-R2（Lite）
Dimensions:	L / W / H: 6.97 in./3.03 in./x7.64 in.（17.7cm/7.7cm/19.4cm）			
Weight:	3.97lbs（1.8 kg）			
Nominal sound level	Nominal sound pressure level: 42.3 dBA (at setting 2) Maximum sound power level: 57.9 dBA (at maximum flow setting S) Maximum sound pressure level: 50.5 dBA (at maximum flow setting S) Typical alarm sound pressure level: 58.8-60.9 dBA (Measured at lowest and highest flow settings, inside the carry bag) (Sound pressures measured at 1 meter per ISO 3744)			
Warm up time	2min			
Oxygen concentration	90% - 3% /+ 5.5% at all settings			
Inspiratory trigger sensitivity	<0.12 cmH2O			
Flow control settings	Pulse dose setting 1,2,3,4,5,6,S	Pulse dose setting 1,2,3,4,5,6	Pulse dose setting 1,2,3,4,5	Pulse dose setting 1,2,3,4
Bolus setting and size per bolus	See table below. Based upon Breath rate and setting. Total delivered: 210 to 1470 ml/min			
Maximum outlet pressure	<28.9 PSI (199 kPa)			
AC Power	100 to 240 VAC, 100VA, 50 to 60 Hz Auto-Sensing: 2.0-1.0A			
DC Power	13.0-16.8 VDC, 100W Max voltage: 12.0 -16.8 VDC (± 0.5) Hardware-compatible only. DC operation requires manufacturer-authorized accessories, which are not currently available.			
Battery type	Lithium Ion			

Rechargeable battery	14.4V 6500mAh
Battery re-charge time	up to 2hrs (100W Type-C super fast charge)
Battery Duration	1.5-4.5 hrs
Operating temperature*	23 to 104°F (-5 to 40°C)
Operating atmospheric pressure	54 kPA to 106 kPA
Operating altitude**	0 to 16,400 ft (0 to 5000 meters)
Operating humidity	5% to 90%, non-condensing
Shipping and storage temperature	-31 to 158˚F (-35 to 70˚C)
Shipping and storage humidity	Up to 90%, non-condensing Store in a dry environment
Measurement uncertainties	Pulse volumes: ± 15% of rated volume Pressure: ± 0.03 psig (General) / ± 0.05 cm H2O (Inspiratory Trigger Sensitivity) Oxygen concentration: ± 3% (not accounting for temperature, barometric pressure, and time from measurement device calibration)
*Based on atmospheric pressure of 14.7 psi (101 kPa) at 68°F (20°C) & Dry (STPD) ** Operating outside of these operational specifications can limit the concentrator's ability to meeting Oxygen Concentration specification at higher liter flow settings.	

Pulse Volumes at Flow Settings

BREATHS PER MINUTE	Setting 1	Setting 2	Setting 3	Setting 4	Setting 5	Setting 6	Setting S
10	21.0	42.0	63.0	84.0	105.0	126.0	147.0
15	14.0	28.0	42.0	56.0	70.0	84.0	98.0
20	10.5	21.0	31.5	42.0	52.5	63.0	73.5
25	8.4	16.8	25.2	33.6	42.0	50.4	58.8
30	7.0	14.0	21.0	28.0	35.0	42.0	49.0
35	6.0	12.0	18.0	24.0	30.0	36.0	42.0
40	5.3	10.6	15.8	21.0	26.3	31.5	36.8

TOTAL VOLUME PER MINUTE (ml/min)	210	420	630	840	1050	1260	1470
	Note: W-R1 (MAX) has 7 pulse flow settings 1, 2, 3, 4, 5, 6,S W-R2 has 6 pulse flow settings 1, 2, 3, 4, 5, 6 W-R2 has 5 pulse flow settings 1, 2, 3, 4, 5 W-R2 (Lite) has 4 pulse flow settings 1, 2, 3, 4						

VI. Intended Use/Indications for Use

The Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to adult patients requiring respiratory therapy on a prescriptive basis. It may be used at home, in institution, vehicle, train, airplane, boats and other transport modalities. This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.

Users should follow their doctor's advice on setting the oxygen flow rate and should not adjust the flow rate without consulting a healthcare professional.

Note: Patients should regularly consult with their physician to evaluate the need for adjustments in their oxygen therapy settings.

VII.Comparison of Technological Characteristics and Performance with the Predicate

Table 1. General Comparison with Predicate Device

Item	Subject Device	Predicate Device	Equivalence Comparison
	Portable oxygen concentrator W-R1(MAX), W-R1, W-R2, W-R2(Lite)	**K230052 Inogen Rove 6 Portable Oxygen Concentrator**	
Product Code	CAW	CAW	**Same**
Classification Name	Generator, oxygen portable	Generator, oxygen portable	**Same**
Regulation Number	21 CFR 868.5440	21 CFR 868.5440	**Same**
Class	Class II	Class II	**Same**
Intended Use/ Indications for Use	The Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to adult patients requiring respiratory therapy on a prescriptive basis. It may be used at home, in institution, vehicle, train, airplane, boats and other transport modalities. This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.	The Inogen Rove 6 Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in the home, institution, and transport modalities. This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.	**Same-Subject device specifies adult use as a subset of predicate indication.**
Prescriptive	YES	YES	**Same**
Fundamental scientific technology	• Breath detection technology • Molecular sieve/pressure swing adsorption technology	• Breath detection technology • Molecular sieve/pressure swing adsorption technology	**Same**
User/Patient Interface	User interface panel	User interface panel	**Same**
	LCD Display to convey information about operating status in numbers and symbols.	LCD Display to convey information about operating status in numbers and symbols.	**Same**
	Alarm Indicator – yellow LED light on UIP that illuminates to indicate abnormal operating conditions in	Alarm Indicator – yellow LED on UIP above “Alarm/Warning” triangle symbol that illuminates to	**Similar**

	compliance with ISO 60601-1-8.	indicate abnormal operating conditions in compliance with ISO 60601-1-8.	
	Breath Detect Notification – Green LED on UIP illuminates when a breath is detected, and an oxygen pulse is triggered.	Breath Detect Notification – Green LED on UIP illuminates when a breath is detected, and an oxygen pulse is triggered.	**Same**
	Auditory Speaker – Audible beeps are emitted to indicate alarm or status change conditions in compliance with ISO 60601-1-8.	Auditory Speaker – Audible beeps are emitted to indicate alarm or status change conditions in compliance with ISO 60601-1-8.	**Same**
	Battery release latch – Patient removable battery using push latch to release battery then slide off bottom of concentrator.	Battery release latch – Patient removable battery using push latch to release battery then slide off bottom of concentrator.	**Same**
	Sieve beds – Users may contact the equipment device provider to arrange for service and/or order a new one.	Sieve beds – Users may send device to provider for sieve bed replacement, or users may replace sieves. Sieve beds are user replaceable by pulling the wire handle while depressing the retaining tab to pull the columns out. The replacement columns are installed by pushing them in until the retaining tab snaps into place.	**Similar - The predicate device allows users to replace the sieve beds themselves, whereas the proposed device requires users to contact the equipment provider for service or replacement.**
	Air inlet grille (Particle Filter) - Patient instructed to clean air inlet grille once per week.	Particle Filter - Patient instructed to clean particle filters once per week.	**Same**

	Optional accessories - Carry Bag with belt, strap, double shoulder straps.	Optional accessories - Carry Bag, Backpack, Cart, External Battery Charger.	**Similar**
	External Battery Charger (EBC) - None	External Battery Charger (EBC) - Optional accessory. Independent battery charger that utilizes an AC/DC power supply. The EBC slides onto the Inogen Rove 6 battery to charge outside of the concentrator.	**Different**
	Mobile Application – None	Inogen Connect Mobile Application – Optional mobile application for viewing device settings, battery information, and current alerts, available for iOS and Android in English, French.	**Different**
	User Manual – Device information including Indications for Use, Contraindications and Precautions, Operating Principles, Cautions and Warnings, Device Descriptions, General Instructions, Audible and Visible Signals, Alarm/Alert System, Troubleshooting, Cleaning, Care and Maintenance, and Specifications and Technical Description	User Manual – Device information including Indications for Use, Contraindications and Precautions, Operating Principles, Cautions and Warnings, Device Descriptions, General Instructions, Audible and Visible Signals, Alarm/Alert System, Troubleshooting, Cleaning, Care and Maintenance, and Specifications and Technical Description	**Same**
Operating System	Software monitored	Software monitored	**Same**
Bluetooth technology	None	Inogen Connect App – BLE Connection to Android or iPhone. The Inogen Rove 6 Oxygen Concentrator is capable of Bluetooth functionality with the Inogen Connect App.	**Different**
Components	AC power adapter/AC power supply – Utilizes 100-240VAC, 50/60Hz power supply and cord for power and charging with wall adapter and USB-Type C connection to concentrator.	AC/DC power adapter - Utilizes 100-240V, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator.	**Different**

	DC Power Cable - None (Hardware compatible with 13.0-16.8 VDC input, but no DC cable or approved accessory available at this time)	DC Power Cable – cord and adapter to allow for connection to 12-volt DC outlet with cigarette lighter connector and barrel jack connection to concentrator.	**Different**
	Cannula - Patient breaths through off the shelf nasal cannula attached to a recessed metal cannula barb on the concentrator. The portal oxygen concentrator is compatible with standard nasal cannulas. (Nasal cannula is not included and must be sourced separately.)	Cannula - Patient breaths through off the shelf nasal cannula attached to a recessed metal cannula barb on the concentrator. The nasal cannula is provided with the Inogen Rove 6.	**Different**
	Battery - utilizes an 8-cell lithium battery. To attach the battery, slide it on to the base of the concentrator. Battery release latch - Patient removable battery by pressing and holding the battery latch button and slide the battery off the device.	Battery - utilizes an 8 or 16-cell lithium battery. To attach the battery, slide it on to the base of the concentrator. Battery release latch - Patient removable battery by pressing and holding the battery latch button and slide the battery off the device.	**Different**
Size	With standard 8-cell battery: L/W/H:6.97” ,3.03” ,7.64”	With standard 8-cell battery: 8.1” H, 3.3” W, 7.2” D	**Different**
Principle of operation	The Portable Oxygen Concentrator uses molecular sieve/pressure swing adsorption technology. Ambient air is drawn through particle filters by a compressor and forced through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. The airflow is then changed, and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Oxygen is collected in an accumulator reservoir. Waste nitrogen is exhausted back into the room. A series of sieve beds, manifolds and precision valves, sensors and embedded software are used to control the cycle to make the system function. Oxygen is delivered to the patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle.	The Inogen Rove 6 Portable Oxygen Concentrator uses molecular sieve/pressure swing adsorption technology. Ambient air is drawn through particle filters by a compressor and forced through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. The airflow is then changed, and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Oxygen is collected in an accumulator reservoir. Waste nitrogen is exhausted back into the room. A series of sieve beds, manifolds and precision valves, sensors and embedded software are used to control the cycle to make the system function. Oxygen is delivered to the	**Same**

<table>
<tr><td></td><td>This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. The Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, through a final filter, into the connected nasal cannula and on to the patient.</td><td>patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. Inogen Rove 6 Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, through a final filter, into the connected nasal cannula and on to the patient.</td><td></td></tr>
<tr><td colspan="4">Performance</td></tr>
<tr><td>Oxygen Delivery Mode</td><td>Pulse Dose</td><td>Pulse Dose</td><td>Same</td></tr>
<tr><td>Output flow</td><td>
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<tr><th>BREATHS PER MINUTE</th><th>Setting1</th><th>Setting2</th><th>Setting3</th><th>Setting4</th><th>Setting 5</th><th>Setting 6</th><th>Setting S</th></tr>
<tr><td>10</td><td>21.0</td><td>42.0</td><td>63.0</td><td>84.0</td><td>105.0</td><td>126.0</td><td>147.0</td></tr>
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	Total volume minute(ml/min)	210	420	630	840	1050	1260	1470	**Total volume minute(ml/min)**	210	420	630	840	1050	1260	
	Note: W-R1 (MAX) has 7 pulse flow settings 1, 2, 3, 4, 5, 6, S W-R2 has 6 pulse flow settings 1, 2, 3, 4, 5, 6 W-R2 has 5 pulse flow settings 1, 2, 3, 4, 5 W-R2 (Lite) has 4 pulse flow settings 1, 2, 3, 4														
Maximum outlet pressure	< 28.9 PSI (199 kPa)								< 28.9 PSI (199kPa)							**Same**
Oxygen Purity	90% - 3% /+ 5.5% at all settings								90% -3%/+6% at all settings							**Different**
Nominal sound level	● Nominal sound pressure level: 42.3 dBA (at setting 2) ● Maximum sound power level: 57.9 dBA (at maximum flow setting S) ● Maximum sound pressure level: 50.5 dBA (at maximum flow setting S) ● Typical alarm sound pressure level: 58.8-60.9 dBA (Measured at lowest and highest flow settings, inside the carry bag) The subject device has a fixed alarm volume.								● 39 dBA typical at setting 2 (MDS-Hi) ● Maximum system sound power of 62 dBA ● Maximum system sound pressure of 54 dBA ● Typical lowest alarm sound pressure of 62.3 dBA (Measured in the carry bag) ● Typical highest alarm sound pressure of 67.5 dBA (Measured in the carry bag)							**Different**
Performance Standards																
Performance and Electrical Safety	• IEC 60601-1:2005+AMD1:2012+AMD2:2020 • IEC 60601-1-2: 2014+AMD1: 2020 • IEC 60601-1-6:2010, AMD1:2013, AMD2:2020 • IEC 60601-1-8:2006/A1: 2012/ A2:2020 • IEC 60601-1-11:2015+AMD1:2020 • ISO 80601-2-69:2020								• IEC 60601-1:2012 • IEC 60601-1-2: 2012 • IEC 60601-1-6:2020 • IEC 60601-1-8:2012 • IEC 60601-1-11:2015 • ISO 80601-2-69:2020							**Different**

	• ISO 80601-2-67:2020	• ISO 80601-2-67:2020 • IEC 62366-1	
Communications			
Power / Energy Source	AC power adapter/AC power supply – Utilizes 100-240VAC, 50/60Hz power supply and cord for power and charging with wall adapter and USB-Type C connection to concentrator. DC Power Cable - None Battery - utilizes an 8-cell lithium battery.	AC/DC Power Adapter – Utilizes 100-240V, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator. DC Power Cable – cord and adapter to allow for connection to 12-volt DC outlet with cigarette lighter connector and barrel jack connection to concentrator. Battery – utilizes an 8 or 16-cell lithium battery.	**Different**
Biocompatibility	Externally Communicating, Tissue, Permanent Duration (>30 days) ISO 18562-2: 2024 Particulate matter ISO 18562-3:2024Volatile organic compounds	Externally Communicating, Tissue, Permanent Duration (>30 days) ISO 18562-2: 2017 Particulate matter ISO 18562-3:2017 Volatile organic compounds	**Same**

The Portable Oxygen Concentrator (W-R1(MAX)) has a higher maximum pulse flow than the predicate device (Inogen Rove 6) but remains within the FDA-cleared range. To further substantiate this, we reference the GCE Zen-O (K162433), an FDA-cleared device with a higher maximum pulse flow than our subject device.

The inclusion of this reference device demonstrates:

- Higher pulse flow has been FDA-cleared – The GCE Zen-O confirms that higher pulse flow rates can be considered safe and effective.
- The subject device remains within a safe range – While its pulse flow is higher than the predicate device, it is still lower than the reference device, ensuring no new concerns regarding safety or effectiveness.

This comparison further supports the substantial equivalence of the subject device.

Table 2 Performance Comparison with Reference Device

<table>
<tr><th rowspan="2">Item</th><th colspan="8">Subject Device</th><th colspan="7">Reference Device</th><th rowspan="2">Remark</th></tr>
<tr><th colspan="8">Portable oxygen concentrator
W-R1(MAX), W-R1, W-R2, W-R2(Lite)</th><th colspan="7">K162433
GCE Zen-O Portable Oxygen Concentrator Model
RS-00500</th></tr>
<tr><td>Output flow</td><td colspan="8"><table>
<tr><th>BREATHS PER MINUTE</th><th>Setting1</th><th>Setting2</th><th>Setting3</th><th>Setting4</th><th>Setting 5</th><th>Setting 6</th><th>Setting S</th></tr>
<tr><td>10</td><td>21.0</td><td>42.0</td><td>63.0</td><td>84.0</td><td>105.0</td><td>126.0</td><td>147.0</td></tr>
<tr><td>15</td><td>14.0</td><td>28.0</td><td>42.0</td><td>56.0</td><td>70.0</td><td>84.0</td><td>98.0</td></tr>
<tr><td>20</td><td>10.5</td><td>21.0</td><td>31.5</td><td>42.0</td><td>52.5</td><td>63.0</td><td>73.5</td></tr>
<tr><td>25</td><td>8.4</td><td>16.8</td><td>25.2</td><td>33.6</td><td>42.0</td><td>50.4</td><td>58.8</td></tr>
<tr><td>30</td><td>7.0</td><td>14.0</td><td>21.0</td><td>28.0</td><td>35.0</td><td>42.0</td><td>49.0</td></tr>
<tr><td>35</td><td>6.0</td><td>12.0</td><td>18.0</td><td>24.0</td><td>30.0</td><td>36.0</td><td>42.0</td></tr>
<tr><td>40</td><td>5.3</td><td>10.6</td><td>15.8</td><td>21.0</td><td>26.3</td><td>31.5</td><td>36.8</td></tr>
<tr><td>Total volume minute(ml/</td><td>210</td><td>420</td><td>630</td><td>840</td><td>1050</td><td>1260</td><td>1470</td></tr>
</table></td><td colspan="7">Pulse mode<table>
<tr><th>BREATHS PER MINUTE</th><th>Setting1</th><th>Setting2</th><th>Setting3</th><th>Setting4</th><th>Setting 5</th><th>Setting 6</th></tr>
<tr><td>15</td><td>11</td><td>22</td><td>33</td><td>44</td><td>55</td><td>66</td></tr>
<tr><td>20</td><td>11</td><td>22</td><td>33</td><td>44</td><td>55</td><td>66</td></tr>
<tr><td>25</td><td>11</td><td>22</td><td>33</td><td>44</td><td>55</td><td>66</td></tr>
<tr><td>30</td><td>11</td><td>22</td><td>33</td><td>44</td><td>55</td><td>66</td></tr>
<tr><td>35</td><td>11</td><td>22</td><td>33</td><td>44</td><td>55</td><td>57</td></tr>
<tr><td>40</td><td>11</td><td>22</td><td>33</td><td>44</td><td>50</td><td>50</td></tr>
</table>All values +/- 15% over all operating conditions</td><td>Different</td></tr>
</table>

	min)									

Note:

W-R1 (MAX) has 7 pulse flow settings 1, 2, 3, 4, 5, 6, S

W-R2 has 6 pulse flow settings 1, 2, 3, 4, 5, 6

W-R2 has 5 pulse flow settings 1, 2, 3, 4, 5

W-R2 (Lite) has 4 pulse flow settings 1, 2, 3, 4

Discussion of Substantial Equivalence

Predicate Inogen Rove 6 Portable Oxygen Concentrator K230052

Decision 1: Is the predicate device legally marketed?

Yes. The predicate device is a legally marketed device as K230052 was cleared on June 30, 2023.

Decision 2: Do the devices have the same intended use?

Yes, the devices have the same intended use.

The subject device specifies use in adult patients only, which represents a subset of the patient population for the predicate device. This clarification does not alter the therapeutic intent or raise new questions of safety or effectiveness. Therefore, it does not constitute a new intended use under the FDA's substantial equivalence framework.

Decision 3: Do the devices have the same technological characteristics?

No, the subject and predicate device have the same technological characteristics as shown.

- Fundamental scientific technology
- User/Patient Interface: panel, LCD Display, breath detect notification, auditory speaker, battery release latch， Air inlet grille (Particle Filter)
- Operating system

- Principle of operation
- Oxygen delivery mode
- Maximum outlet pressure

Similar technological characteristics are shown.

- User/Patient Interface: alarm indicator, sieve beds, optional accessories, user manual

Decision 4: Do the different technological characteristics of the devices raise different questions of safety and effectiveness?

No. The details of the characteristics for which the subject device was shown to be the same, similar, and different to the predicate device was demonstrated. (Table 1) .The discussion of the differences, and decision 5a and 5b shown below support that the differences do not raise different questions of safety and effectiveness.

Characteristic	Portable oxygen concentrator W-R1(MAX), W-R1, W-R2, W-R2(Lite)	K230052 Inogen Rove 6 Portable Oxygen Concentrator	Differences Discussion
User/Patient Interface	External Battery Charger (EBC) - None	External Battery Charger (EBC) - Optional accessory. Independent battery charger that utilizes an AC/DC power supply. The EBC slides onto the Inogen Rove 6 battery to charge outside of the concentrator.	The subject device does not include an external battery charger because the battery can be charged while the concentrator is plugged into an AC power source. In contrast, the predicate device offers an optional external battery charger that allows batteries to be charged separately from the concentrator. This difference does not impact safety or effectiveness, as the subject device ensures continuous operation by allowing the battery to charge while in use, eliminating the need for a separate external charger. The difference in this technological characteristic does not raise different questions of safety and effectiveness.
	Mobile Application – None	Inogen Connect Mobile Application – Optional mobile application for viewing device settings, battery information,	The subject device does not have an optional mobile application while the predicate device does have a optional mobile application. The difference in this technological characteristic does not raise different questions of safety and

		and current alerts, available for iOS and Android in English, French.	effectiveness.
Bluetooth technology	None	Inogen Connect App – BLE Connection to Android or iPhone. The Inogen Rove 6 Oxygen Concentrator is capable of Bluetooth functionality with the Inogen Connect App.	The subject device does not have Bluetooth technology while the predicate device does have Bluetooth technology. The difference in this technological characteristic does not raise different questions of safety and effectiveness.
Components	AC power adapter/AC power supply – Utilizes 100-240VAC, 50/60Hz power supply and cord for power and charging with wall adapter and USB-Type C connection to concentrator.	AC/DC power adapter - Utilizes 100-240V, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator.	The proposed device utilizes a USB Type-C connection for power and charging, whereas the predicate device employs a barrel jack connection. This difference in power connector type does not impact the safety or effectiveness of the device, as both power connection methods provide stable and reliable power delivery to the concentrator. USB Type-C is a widely used and industry-accepted power interface known for its high power efficiency, reversible plug orientation, and durability. It complies with modern power delivery standards and allows for efficient charging and operation. The barrel jack connection used in the predicate device also serves the same fundamental function of supplying power to the device, ensuring continuous operation. Both devices support 100-240V AC, 50/60Hz power supply compatibility, allowing global usage with appropriate adapters. Therefore, despite the difference in power connection type, the core functionality, safety, and effectiveness of the proposed device remain equivalent to the predicate device. The difference in this technological

			characteristic does not raise different questions of safety and effectiveness.
Components	DC Power Cable - None (Hardware compatible with 13.0-16.8 VDC input, but no DC cable or approved accessory available at this time)	DC Power Cable – cord and adapter to allow for connection to 12-volt DC outlet with cigarette lighter connector and barrel jack connection to concentrator.	The subject device hardware supports DC input but no approved DC accessory is provided at this time. The user manual explicitly states that only DC power accessories approved or provided by the manufacturer may be used. This ensures safety and prevents misuse of incompatible components. The difference in this technological characteristic does not raise different questions of safety and effectiveness.
Components	Cannula - Patient breaths through off the shelf nasal cannula attached to a recessed metal cannula barb on the concentrator. The portal oxygen concentrator is compatible with standard nasal cannulas. (Nasal cannula is not included and must be sourced separately.)	Cannula - Patient breaths through off the shelf nasal cannula attached to a recessed metal cannula barb on the concentrator. The nasal cannula is provided with the Inogen Rove 6.	The proposed device features a standard oxygen outlet compatible with commercially available nasal cannulas. Recommended cannula specifications are provided in Section 2.12: Cannula Use of the user manual. This difference does not affect the intended use or fundamental function of the device. The difference in this technological characteristic does not raise different questions of safety and effectiveness.
Components	Battery - utilizes an 8-cell lithium battery. To attach the battery, slide it on to the base of the concentrator. Battery release latch - Patient removable battery by pressing and holding the battery latch button and slide the battery off the device.	Battery - utilizes an 8 or 16-cell lithium battery. To attach the battery, slide it on to the base of the concentrator. Battery release latch - Patient removable battery by pressing and holding the battery latch button and slide the battery off the device.	The portable oxygen concentrator is equipped with a single 8-cell lithium battery, but not a 16-cell lithium battery. The portable oxygen concentrator performs its intended use with the 8-cell lithium battery and the difference in this technological characteristic does not raise different questions of safety and effectiveness.

Size	With standard 8-cell battery: L/W/H:6.97” ,3.03” ,7.64”	With standard 8-cell battery: 8.1” H, 3.3” W, 7.2” D	The Inogen Rove 6 Portable Oxygen Concentrator is lager in size. The difference in size would not raise any issues in safety and effectiveness.
Output flow	See cell above	See cell above	The portable oxygen concentrator has a maximum pulse flow of 1470 ml/min, which is higher than the Inogen Rove 6 Portable Oxygen Concentrator with a maximum pulse flow of 1260 ml/min. However, the GCE Zen-O Portable Oxygen Concentrator (Reference Device) has an even higher maximum pulse flow of 2000 ml/min. This demonstrates that while the proposed device has a slightly higher maximum pulse flow than the Predicate Device, it remains well within the acceptable range of FDA-cleared portable oxygen concentrators. The oxygen delivery mechanism and incremental flow settings remain consistent with standard pulsed delivery systems, ensuring that the intended use and fundamental function of the device are not altered. Therefore, this difference in technological characteristics does not raise new questions of safety or effectiveness.
Oxygen Purity	90%-3%/+ 5.5% at all settings	90% -3%/+6% at all settings	The portable oxygen concentrator utilizes air separation technology to remove nitrogen, achieving an oxygen concentration that is theoretically close to 96%. The stated oxygen purity for the portable oxygen concentrator is 90% -3%/+5.5% at all settings, while the Inogen Rove 6 Portable Oxygen Concentrator specifies 90% -3%/+6% at all settings.This difference arises from a conservative specification approach rather than a fundamental technological variation. In practical use, both devices deliver oxygen purity levels that are functionally equivalent, ensuring consistent performance for users.The difference in this

			technological characteristic does not raise different questions of safety and effectiveness.
Nominal sound level	● Nominal sound pressure level: 42.3 dBA (at setting 2) ● Maximum sound power level: 57.9 dBA (at maximum flow setting S) ● Maximum sound pressure level: 50.5 dBA (at maximum flow setting S) ● Typical alarm sound pressure level: 58.8-60.9 dBA (Measured at lowest and highest flow settings, inside the carry bag) The subject device has a fixed alarm volume.	● 39 dBA typical at setting 2 (MDS-Hi) ● Maximum system sound power of 62 dBA ● Maximum system sound pressure of 54 dBA ● Typical lowest alarm sound pressure of 62.3 dBA (Measured in the carry bag) ● Typical highest alarm sound pressure of 67.5 dBA (Measured in the carry bag)	The subject device has a nominal operating sound pressure level of 42.3 dBA at setting 2, and a maximum sound pressure level of 50.5 dBA and sound power level of 57.9 dBA at the highest flow setting. These values are comparable to those of the predicate device . The subject device has a fixed alarm volume, with measured alarm sound pressure levels ranging from 58.8 to 60.9 dBA across flow settings, tested in the carry bag at a distance of 1 meter. The predicate device features user-adjustable alarm volume, ranging from 62.3 to 67.5 dBA. Although the subject device has a slightly lower alarm sound level, testing confirms that the alarm remains clearly audible under intended use conditions. These differences in alarm configuration (fixed vs. adjustable) and nominal sound levels do not raise different questions of safety or effectiveness.
Performance and Electrical Safety	• IEC 60601-1:2005+AMD1:2012+AMD2:2020 • IEC 60601-1-2: 2014+AMD1: 2020 • IEC 60601-1-6:2010, AMD1:2013, AMD2:2020	• IEC 60601-1:2012 • IEC 60601-1-2: 2012 • IEC 60601-1-6:2020 • IEC 60601-1-8:2012 • IEC 60601-1-11:2015 • ISO 80601-2-69:2020 • ISO 80601-2-67:2020 • IEC 62366-1	IEC 62366-1 is not a mandatory requirement for this device type under FDA regulations. The FDA's *Applying Human Factors and Usability Engineering to Medical Devices guidance* states that human factors validation is necessary when usability errors could lead to significant safety risks. Given the simple operation and low user interaction risk of the subject device, usability considerations are sufficiently addressed under FDA 21 CFR Part 820. Therefore, the

	• IEC 60601-1-8:2006/A1: 2012/ A2:2020 • IEC 60601-1-11:2015+AMD 1:2020 • ISO 80601-2-69:2020 • ISO 80601-2-67:2020		absence of IEC 62366-1 compliance does not impact substantial equivalence.This difference in regulatory compliance does not raise different questions of safety and effectiveness.

VIII. Non-Clinical Tests Summary

Non-clinical performance testing was conducted to verify the portable oxygen concentrator. The following performance data were provided in support of the substantial equivalence determination.

1. **Safety and Performance testing:**
   - **ISO 80601-2-69:2020** and **ISO 80601-2-67:2020**: Evaluated basic safety and essential performance for oxygen concentrators and oxygen-conserving equipment.
   - **Internal Bench Testing:** Assessed **oxygen purity, pulse volume, trigger sensitivity, Operating atmospheric pressures and altitude; Operating temperature; alarm functions, battery life, noise levels, and vibration resistance** under various environmental conditions.
2. **Biocompatibility Testing:**
   - Conducted per **ISO 18562-1:2024, ISO 18562-2:2024, and ISO 18562-3:2024** to evaluate biocompatibility of breathing gas pathways, including emissions of **particulate matter and volatile organic compounds (VOCs).**
3. **Electrical Safety and EMC Testing:**
   - Evaluated per the following IEC 60601 series standards to confirm compliance with medical electrical equipment safety, usability, alarm systems, and electromagnetic disturbance requirements:
     - **IEC 60601-1:2005+AMD1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.**
     - **IEC 60601-1-2:2014+AMD1:2020**, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
     - **IEC 60601-1-6:2010+AMD1:2013+AMD2:2020**, Medical electrical equipment - Part 1-6: General requirements for basic safety and

essential performance - Collateral standard: Usability.

- **IEC 60601-1-8:2006+AMD1:2012**, Medical electrical equipment – Part 1-8: 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.
- **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 and medical electrical systems used in the home healthcare environment.
- **IEC TR 60601-4-2**: **2016** Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

- **Battery Safety Testing (IEC 62133-2:2017/AMD1:2021,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.)** Testing was conducted to ensure that the lithium batteries used in the device comply with safety standards for portable applications.

4. Software Verification and Validation:

- Conducted in accordance with **FDA guidance on premarket submissions** for software in medical devices, assessing software functionality, fault recovery, and all tests met the required safety and performance standards.

IX. Clinical Tests

Animal and clinical testing was not required to demonstrate substantial equivalence.

X. Substantial Equivalence Conclusion

Based on the substantial equivalence table and performance testing, results demonstrate that the portable oxygen concentrator is substantially equivalent to the Inogen Rove 6 portable oxygen concentrator.