June 30, 2023

Inogen, Inc
Carole Harris
Vice President, Regulatory Affairs
301 Coromar Drive
Goleta, California 93117

Re: K230052
Trade/Device Name: Inogen Rove 6 Portable Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: June 1, 2023
Received: June 2, 2023

Dear Carole Harris:

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,

James J. Lee -S

James J. Lee, Ph.D.
Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230052

Device Name
Inogen Rove 6 Portable Oxygen Concentrator

Indications for Use *(Describe)*

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.

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.

510(k) Summary

Date Prepared: June 28, 2023

I **Sponsor:** Inogen, Inc.
301 Coromar Drive
Goleta, California 93117

Sponsor Contact: Carole E.N. Harris
VP Quality & Regulatory Affairs
charris@inogen.net
Phone: 470-757-7036

Submission Correspondent: Carole Harris

Confidentiality
Inogen, Inc requests as outlined under 21 CFR 20.61 that FDA treat this premarket notification and Inogen's intent to market as confidential commercial information.

II **Device**
Proprietary or Trade Name: Inogen Rove 6 Portable Oxygen Concentrator, K230052
Common/Usual Name: Generator, Oxygen, Portable
Regulation Number: 868.5440
Device Class: 2
Product Code: CAW

III **Predicate Device:** Inogen Rove 4 Portable Oxygen Concentrator, K222086
Common/Usual Name: Generator, Oxygen, Portable
Regulation Number: 868.5440
Device Class: 2
Product Code: CAW

IV **Reference Device:** GCE Zen-O Portable Oxygen Concentrator Model RS-00500, K162433
Common/Usual Name: Generator, Oxygen, Portable
Regulation Number: 868.5440
Device Class: 2
Product Code: CAW

IV **Device Description:**
The Inogen Rove 6 Portable Oxygen Concentrator (Inogen Rove 6) is a Class 2, low risk, portable oxygen generator that provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institution, vehicle, and other transport modalities. It is used with a nasal cannula to channel oxygen from the device to the patient. The concentrator and the nasal cannula are non-sterile.

The Inogen Rove 6 Portable Oxygen Concentrator is capable of continuous use in a home, institution, vehicle, and various mobile environments. Power options include 100 – 240 V-AC (50-60Hz) power supply, rechargeable battery packs, or a 13.5 -15.0 V-DC power cable.

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 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. The 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.

The Inogen Rove 6 Portable Oxygen Concentrator utilizes Bluetooth technology that pairs the portable oxygen concentrator to a mobile device or tablet using the Inogen Connect App.

The design of the Inogen Rove 6 Portable Oxygen Concentrator has focused on maximizing subsystem efficiencies and miniaturizing components to enable continuous duty use and to provide minimal weight with battery operation for mobile use.

The basic technology of the Inogen Rove 6 Portable Oxygen Concentrator is equivalent to other approved oxygen concentrators. The principles of operation are equivalent to the predicate device: Inogen Rove 4 Portable Oxygen Concentrator, K222086, and the reference device: GCE Zen-O Portable Oxygen Concentrator Model RS-00500, K162433 noted above.

Image of the Inogen Rove 6 Portable Oxygen Concentrator:

SPECIFICATIONS:

Specifications:	
Mains Isolation	Remove both the DC input cord from device as well as the battery pack.
Dimensions:	
With standard battery	7.2 x 3.3 x 8.1 in (18.2 x 8.3 x 20.7 cm)
With extended battery	7.2 x 3.3 x 9.0 in (18.2 x 8.3 x 22.9 cm)
Weight:	
With standard battery	4.8 pounds (2.2kg)
With extended battery	5.8 pounds (2.6kg)
Nominal sound level	39 dBA at setting 2 (MDS-Hi) Maximum system sound power of 62 dBA Maximum system sound pressure of 54 dBA
Warm up time	2 minutes
Oxygen concentration*	90% -3%/+6% at all settings
Inspiratory trigger sensitivity	<0.12 cmH_2O
Flow control settings	Pulse dose setting 1,2,3,4,5,6
Bolus setting and size per bolus	See table below. Based upon Breath rate and

	setting. Total delivered: 210 to 1260 ml/min
Maximum outlet pressure	<28.5 PSI (199 kPa)
AC Power	100 to 240 VAC, 50 to 60 Hz Autosensing 2.0 – 1.0A
DC Power	13.5-15.0, 24 VDC, 120W Max voltage: 12.0 to 16.8 VDC (± 0.5)
Battery type	Lithium Ion
Rechargeable battery:	12.0 to 16.8 VDC (± 0.5)
Battery re-charge time	Standard (BA-500 & BA-508): up to 3 hours Extended (BA-516): up to 4 hours
Operating temperature**	41 to 104°F (5 to 40°C)
Operating humidity	15% to 90%, non-condensing
Operating altitude**	0 to 10,000 ft (0 to 3048 meters)
Shipping and storage temperature	-13 to 158°F (-25 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.

V Indications for Use:

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 home, institution, vehicle, 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.

VI Comparison of Technological Characteristics and Performance with the Predicate

The table below provides a side-by-side comparison of the Inogen Rove 6 User Interface elements with respect to the predicate device, the Inogen Rove 4. The user interface features are broken down by category and the elements of each category. All Inogen Rove 6 User Interface elements have been found to be substantially equivalent to that of the predicate device, the Inogen Rove 4. Refer to Table 5.1.
All Inogen Rove 6 User Interface elements have been found to be substantially equivalent to that of the reference device, GCE Zen-O Portable Oxygen Concentrator Model RS-00500. Refer to table 5.2

Table 5.1: Comparison of the Predicate device vs. the Subject Device and References

	Predicate Device: Inogen Rove 4	**Subject Device: Inogen Rove 6**	**Comparison**
510K#	K222086	K230052	N/A
Product Code	CAW	CAW	Substantially equivalent
CFR	21 CFR 868.5440	21 CFR 868.5440	Substantially equivalent
Classification	2	2	Substantially equivalent
Indications for Use	The Inogen Rove 4 Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institution, and transport modalities.	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 home, institution, vehicle, and other transport modalities.	Substantially equivalent
Prescriptive	Yes	Yes	Substantially equivalent
Fundamental scientific technology	• Breath detection technology • Molecular Sieve/pressure swing adsorption technology	• Breath detection technology • Molecular Sieve/pressure swing adsorption technology	Substantially equivalent
Patient use	Patients requiring supplemental oxygen	Patients requiring supplemental oxygen	Substantially equivalent
User/Patient Interface	User interface panel	User interface panel	Substantially equivalent
	LCD Display to convey information about operating status in numbers and symbols.	LCD Display to convey information about operating status in numbers and symbols.	Substantially equivalent Setting, battery, and auditory alarm status are displayed.

	Predicate Device: Inogen Rove 4	Subject Device: Inogen Rove 6	Comparison
	Alarm Indicator – yellow LED on UIP above "Alarm/Warning" triangle symbol that illuminates to indicate abnormal operating conditions in compliance with ISO 60601-1-8	Alarm Indicator – yellow LED on UIP above "Alarm/Warning" triangle symbol that illuminates to indicate abnormal operating conditions in compliance with ISO 60601-1-8	Substantially equivalent
	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	Substantially equivalent.
	Auditory Buzzer – 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.	Substantially equivalent.
	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.	Substantially equivalent.
	Sieve beds – Users may send device to provider for sieve bed replacement, or users may replace sieves. Sieve beds are user replaceable using M6 hex Allen key to unscrew and slide out single piece sieve beds, then slide in replacements and screw back into concentrator.	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.	Substantially Equivalent. Both the Inogen Rove 6 and Inogen Rove 4 have user replaceable sieve beds.
	Particle Filter – Patient instructed to clean particle filters once per week.	Particle Filter – Patient instructed to clean particle filters once per week.	Substantially equivalent
	Optional accessories - Carry Bag, Backpack, External Battery Charger, Hip Bag	Optional accessories - Carry Bag, Backpack, Cart, External Battery Charger	Substantially equivalent. Inogen Rove 6 has a cart available for transport, and Inogen Rove 4 has a hip bag.

	Predicate Device: Inogen Rove 4	Subject Device: Inogen Rove 6	Comparison
	External Battery Charger (EBC) – Optional accessory. Independent battery charger that utilizes an AC/DC power supply. The EBC slides onto the Inogen Rove 4 battery to charge outside of the concentrator.	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.	Substantially equivalent. Both Inogen Rove 6 and Inogen Rove 4 batteries can be charged externally from the concentrator.
	Inogen Connect Mobile Application – Optional mobile application for viewing device settings, battery information, and current alerts, available for iOS and Android in English, French.	Inogen Connect Mobile Application – Optional mobile application for viewing device settings, battery information, and current alerts, available for iOS and Android in English, French.	Substantially equivalent
	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	Substantially Equivalent. The Inogen Rove 6 and Inogen Rove 4 User Manuals contain equivalent information for the user.
Operating System	Software monitored	Software monitored	Substantially Equivalent
Bluetooth Technology	Inogen Connect App – BLE Connection to Android or iPhone. The Inogen Rove 4 Oxygen Concentrator is capable of Bluetooth functionality with the Inogen Connect App.	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.	Substantially Equivalent
Components	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.	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.	Substantially equivalent
	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.	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.	Substantially equivalent

	Predicate Device: Inogen Rove 4	Subject Device: Inogen Rove 6	Comparison
	Cannula -- Patient breaths through off the shelf nasal cannula attached to a recessed metal cannula barb on the concentrator.	Cannula -- Patient breaths through off the shelf nasal cannula attached to a recessed metal cannula barb on the concentrator.	Substantially equivalent
	Battery – utilizes a 4 or 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.	Substantially equivalent. Rove 6 is compatible with larger battery sizes.
Size	With 8-cell battery: 8.1”H x 2.7”W x 5.9”D	With standard 8-cell battery: 8.1” H, 3.3” W, 7.2” D	Similar: Rove 6 is larger
Principle of Operation	The Inogen Rove 4 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. 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.	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 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.	Substantially equivalent
Performance			
Oxygen Delivery Mode	Pulse Dose	Pulse Dose	Substantially equivalent.

<table>
<tr><th></th><th>Predicate Device: Inogen Rove 4</th><th>Subject Device: Inogen Rove 6</th><th>Comparison</th></tr>
<tr><td>Output Flow</td><td>
<table>
<tr><th>BREATHS PER MINUTE</th><th>Setting 1</th><th>Setting 2</th><th>Setting 3</th><th>Setting 4</th></tr>
<tr><td>10</td><td>21.0</td><td>42.0</td><td>63.0</td><td>84.0</td></tr>
<tr><td>15</td><td>14.0</td><td>28.0</td><td>42.0</td><td>56.0</td></tr>
<tr><td>20</td><td>10.5</td><td>21.0</td><td>31.5</td><td>42.0</td></tr>
<tr><td>25</td><td>8.4</td><td>16.8</td><td>25.2</td><td>33.6</td></tr>
<tr><td>30</td><td>7.0</td><td>14.0</td><td>21.0</td><td>28.0</td></tr>
<tr><td>35</td><td>6.0</td><td>12.0</td><td>18.0</td><td>24.0</td></tr>
<tr><td>40</td><td>5.25</td><td>10.5</td><td>15.75</td><td>21.0</td></tr>
<tr><td>TOTAL VOLUME PER MINUTE (ml/min)</td><td>210</td><td>420</td><td>630</td><td>840</td></tr>
</table>
</td><td>
<table>
<tr><th>BREATHS PER MINUTE</th><th>Setting 1</th><th>Setting 2</th><th>Setting 3</th><th>Setting 4</th><th>Setting 5</th><th>Setting 6</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></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></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></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></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></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></tr>
<tr><td>40</td><td>5.25</td><td>10.5</td><td>15.75</td><td>21.0</td><td>26.3</td><td>31.5</td></tr>
<tr><td>TOTAL VOLUME PER MINUTE (ml/min)</td><td>210</td><td>420</td><td>630</td><td>840</td><td>1050</td><td>1260</td></tr>
</table>
</td><td>Similar: Rove 6 has 2 additional flow settings, delivering a higher maximum output.</td></tr>
<tr><td>Oxygen Purity</td><td>90% - 3%/+6% at all settings</td><td>90% - 3%/+6% at all settings</td><td>Substantially equivalent.</td></tr>
<tr><td>Maximum Outlet Pressure</td><td>< 22 PSI
18.7 PSI (129 kPa) ± 10%</td><td><28.9 PSI (199 kPa)</td><td>Similar

Rove 6 has a higher maximum outlet pressure which falls below the FAA maximum oxygen pressure restriction. Test results for the Rove 6 demonstrate actual outlet pressures in the range of 24-25 PSI. Difference discussed further in Section VIII.</td></tr>
<tr><td colspan="4">Performance Standards</td></tr>
<tr><td>Performance Electrical Safety and EMC</td><td>• IEC 60601-1:2012
• IEC 60601-1-2: 2012</td><td>• IEC 60601-1:2012
• IEC 60601-1-2: 2012</td><td>Substantially equivalent.</td></tr>
</table>

	Predicate Device: Inogen Rove 4	Subject Device: Inogen Rove 6	Comparison
	• 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 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	No difference.
Communications			
Power / Energy Source	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 a 4 or 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.	Substantially equivalent. Inogen Rove 6 is compatible with larger batteries.
Biocompatibility	Externally Communicating, Tissue, Permanent Duration (>30 days) ISO 18562-2: 2017 Particulate matter ISO 18562-3:2017 Volatile organic compounds	Externally Communicating, Tissue, Permanent Duration (>30 days) ISO 18562-2: 2017 Particulate matter ISO 18562-3:2017 Volatile organic compounds	Substantially equivalent. No Difference.

Table 5.2: Comparison of the Reference device vs. the Subject Device and References

	Reference Device: Oxus GCE Zen-O	Subject Device: Inogen Rove 6	Comparison
510K#	K162433	K230052	N/A
Product Code	CAW	CAW	Substantially equivalent
CFR	21 CFR 868.5440	21 CFR 868.5440	Substantially equivalent
Classification	2	2	Substantially equivalent
Indications for Use	The Portable Oxygen Concentrator is intended to provide supplemental oxygen in a home, institutional, or travel environment.	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 home, institution, and transport modalities.	Substantially equivalent
Prescriptive	Yes	Yes	Substantially equivalent
Fundamental scientific technology	• Breath detection technology • Molecular Sieve/pressure swing adsorption technology	• Breath detection technology • Molecular Sieve/pressure swing adsorption technology	Substantially equivalent
Patient use	Adult patients with chronic pulmonary diseases such as chronic bronchitis, emphysema, asthma, or lung cancer, those in the terminal stage of cancer, or any patient requiring supplemental oxygen.	Patients requiring respiratory therapy on a prescriptive basis.	Similar. Reference device mentions specific adult patients as well as any patient requiring supplemental oxygen. Rove 6 is substantially equivalent to the predicate Rove 4 device.
User/Patient Interface	User interface panel	User interface panel	Substantially equivalent
	LCD Display to convey information about operating status in numbers and symbols.	LCD Display to convey information about operating status in numbers and symbols.	Substantially equivalent Setting, battery, and auditory alarm status are displayed.
	Alarm Indicator – yellow LED on UIP above “Alarm/Warning” triangle symbol that illuminates to indicate abnormal operating conditions in compliance with ISO 60601-1-8	Alarm Indicator – yellow LED on UIP above “Alarm/Warning” triangle symbol that illuminates to indicate abnormal operating conditions in compliance with ISO 60601-1-8	Substantially equivalent
	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	Substantially equivalent.

	Reference Device: Oxus GCE Zen-O	Subject Device: Inogen Rove 6	Comparison
	Auditory Buzzer – 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.	Substantially equivalent. Both meet sound levels compliant to the standard.
	Battery release button – Patient removable battery using push button to release battery then slide out of top of concentrator.	Battery release latch – Patient removable battery using push latch to release battery then slide off bottom of concentrator.	Substantially equivalent.
	Sieve module is an internal component and is only replaceable by a trained person.	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. Both the Inogen Rove 6 and Oxus GCE Zen-O have replaceable sieve beds. Inogen Rove 6 and the predicate device offers the convenience of user replaceable sieve beds.
	Particle Filter – Patient instructed to clean particle filters once per week.	Particle Filter – Patient instructed to clean particle filters once per week.	Substantially equivalent
	Accessories - Carry Bag, Cart, Battery, Accessory Bag, Rechargeable battery, External battery charger, humidifier kit	Optional accessories - Carry Bag, Backpack, Cart, External Battery Charger	Substantially equivalent.
	External Battery Charger (EBC) –The battery can be charged inside the concentrator when installed into the concentrator that is connected to the AC/DC power supply, or outside of the concentrator in the approved EBC.	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.	Substantially equivalent. Both Inogen Rove 6 and GCE Zen-O batteries can be charged externally from the concentrator.
	Mobile Application not available.	Inogen Connect Mobile Application – Optional mobile application for viewing device settings, battery information, and current alerts, available for iOS and Android in English, French.	Similar Inogen Rove 6 allows concentrator information to be viewed on a mobile device as well as on the concentrator display. The same information is available on

	Reference Device: Oxus GCE Zen-O	Subject Device: Inogen Rove 6	Comparison
			the Oxus GCE Zen-O concentrator display only.
	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	Substantially Equivalent. The Inogen Rove 6 and Inogen Rove 4 User Manuals contain equivalent information for the user.
Operating System	Software monitored	Software monitored	Substantially Equivalent
Bluetooth Technology	N/A	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.	Similar Inogen Rove 6 allows concentrator information to be viewed on a mobile device as well as on the concentrator display. The same information is available on the Oxus GCE Zen-O concentrator display only.
Components	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.	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.	Substantially equivalent
	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.	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.	Substantially equivalent
	Cannula -- Patient breaths through off the shelf 4', 7', 25' or 50' nasal cannula attached to a recessed metal cannula barb on the concentrator.	Cannula -- Patient breaths through off the shelf nasal cannula attached to a recessed metal cannula barb on the concentrator.	Substantially equivalent
	Battery – Utilizes one or two or rechargeable lithium batteries. To attach the battery, slide it into the top of the concentrator. Two batteries can be placed in the concentrator battery slots or one battery can be placed in either slot.	Battery – utilizes an 8 or 16-cell lithium battery. To attach the battery, slide it on to the base of the concentrator.	Substantially equivalent.

	Reference Device: Oxus GCE Zen-O	Subject Device: Inogen Rove 6	Comparison
	Battery release button – Patient removable battery using push button to release battery then slide out of top of concentrator.	Battery release latch – Patient removable battery by pressing and holding the battery latch button and slide the battery off the device.	Rove 6 is compatible with larger battery sizes.
Size	12.3”H x 8.3”W x 6.6”D	With standard 8-cell battery: 8.1” H, 3.3” W, 7.2” D	Similar: Rove 6 is smaller
Weight	10.25 lbs	With Standard Battery: 4.8 lbs With Extended Batter: 5.8 lbs	Inogen Rove 6 is substantially lighter in weight.
Principle of Operation	The GCE Zen-O 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 mode, continuous mode Auto Mode or ECO Mode basis in precise amounts during the inhalation part of the breathing cycle. In standard Pulse Mode, the device will give you the same amount of oxygen every breath, regardless of your breath rate. This can consume more battery power at higher breath rates. In Eco Mode, the device will deliver a fixed volume of oxygen per minute regardless of breath rate, and will give an extended battery duration. In Auto Mode: If no inhalation is detected for 60 seconds when in pulse mode, the “Check Cannula” alarm will be activated and the device will automatically enter Auto-Mode and continue to deliver oxygen at a rate of 18 breaths per minute. When an inhalation is detected, the device will clear the “Check Cannula” alarm and exit Auto-Mode.	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 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.	Substantially equivalent
Performance			
Oxygen Delivery Mode	Pulse Dose, Eco Mode, Auto Mode, Continuous Mode Flow	Pulse Dose	Similar: Rove 6 offers pulse dose mode.

<table>
<tr><th></th><th>Reference Device: Oxus GCE Zen-O</th><th>Subject Device: Inogen Rove 6</th><th>Comparison</th></tr>
<tr><td>Output Flow</td><td>Pulse mode
<table>
<tr><th>BREATHS PER MINUTE</th><th>Setting 1</th><th>Setting 2</th><th>Setting 3</th><th>Setting 4</th><th>Setting 5</th><th>Setting 6</th></tr>
<tr><td>15</td><td>14.0</td><td>28.0</td><td>42.0</td><td>56.0</td><td>55</td><td>66</td></tr>
<tr><td>20</td><td>10.5</td><td>21.0</td><td>31.5</td><td>42.0</td><td>55</td><td>66</td></tr>
<tr><td>25</td><td>8.4</td><td>16.8</td><td>25.2</td><td>33.6</td><td>55</td><td>66</td></tr>
<tr><td>30</td><td>7.0</td><td>14.0</td><td>21.0</td><td>28.0</td><td>55</td><td>66</td></tr>
<tr><td>35</td><td>6.0</td><td>12.0</td><td>18.0</td><td>24.0</td><td>55</td><td>66</td></tr>
<tr><td>40</td><td>5.25</td><td>10.5</td><td>15.75</td><td>21.0</td><td>50</td><td>50</td></tr>
</table>
All values +/- 15% over all operating conditions</td><td>
<table>
<tr><th>BREATHS PER MINUTE</th><th>Setting 1</th><th>Setting 2</th><th>Setting 3</th><th>Setting 4</th><th>Setting 5</th><th>Setting 6</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></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></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></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></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></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></tr>
<tr><td>40</td><td>5.25</td><td>10.5</td><td>15.75</td><td>21.0</td><td>26.3</td><td>31.5</td></tr>
<tr><td>TOTAL VOLUME PER MINUTE (ml/min)</td><td>210</td><td>420</td><td>630</td><td>840</td><td>1050</td><td>1260</td></tr>
</table></td><td>Similar: Both devices offer six (6) settings, but the Inogen Rove 6 delivers a set output per minute (ml/min) whereas the Zen-O delivers a set output per breath (ml/breath).
When comparing the total output per minute, the maximum output from the Inogen Rove 6 (1260 ml/min) is similar to the Zen-O setting 6 at 20 breaths/min, (20 breath/min x 66ml/min = 1320 ml/min). Zen-O highest output is setting 6 at 35 breath/min, totaling 2310 mil/min.</td></tr>
<tr><td>Oxygen Purity</td><td>90% - 3%/+6% at all settings</td><td>90% - 3%/+6% at all settings</td><td>Substantially equivalent.</td></tr>
<tr><td>Maximum Outlet Pressure</td><td>20.5 PSI</td><td><28.9 PSI (199 kPa)</td><td>Similar

Rove 6 has a higher maximum outlet pressure which falls below the FAA maximum oxygen pressure restriction. Test results for the Rove 6 demonstrate actual outlet pressures in the range of 24-25 PSI. Difference discussed further in Section VIII.</td></tr>
<tr><td colspan="4">Performance Standards</td></tr>
</table>

	Reference Device: Oxus GCE Zen-O	Subject Device: Inogen Rove 6	Comparison
Performance Electrical Safety and EMC	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-6 • IEC 60601-1-8 • IEC 60601-1-11 • ISO 80601-2-69 • ISO 80601-2-67 • Usability testing was performed. Unknown per IEC 62366-1	• 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	Similar. Usability was conducted on the Inogen Rove 6 per IEC 62366-1.
Communications			
Power / Energy Source	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 to concentrator. Battery – utilizes a rechargeable 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 rechargeable lithium battery.	Substantially equivalent.
Biocompatibility	Externally Communicating, Tissue, Limited duration (≤ 24h) ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"	Externally Communicating, Tissue, Permanent Duration (>30 days) ISO 18562-2: 2017 Particulate matter ISO 18562-3:2017 Volatile organic compounds	Similar. Inogen Rove 6 was tested per the duration of patient contact.

VII Substantial Equivalence Discussion

Intended Use/ Indications for Use

The Inogen Rove 6, the Inogen Rove 4 and the Oxus GCE Zen-O have similar Intended Use/Indications for use. Both devices provide a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. They both may be used in home, institution, vehicle, and other transport modalities.

Technological Characteristics and Principles of Operation

The Inogen Rove 6, the Inogen Rove 4 and the Oxus GCE Zen-O operate on Pressure Swing Adsorption (PSA) technology to produce oxygen and deliver it to the patient via a standard nasal cannula. They deliver a bolus of oxygen upon sensing a pressure change at the start of inhalation.

There are no differences which raise different questions of safety or effectiveness.

Non-clinical Testing

Inogen performed testing to demonstrate and support safety and effectiveness when compared to the predicate and the applicable standards.

Testing included:
- ISO 80601-2-69 - Medical Electrical Equipment - Part 2-69: Particular Requirements For Basic Safety And Essential Performance Of Oxygen Concentrator Equipment
- ISO 80601-2-67 - Medical Electrical Equipment - Part 2-67: Particular Requirements For Basic Safety And Essential Performance Of Oxygen-Conserving Equipment

Bench Testing included:
- Pulse, volume; Pulse Time; Trigger Sensitivity; Oxygen Purity under various conditions; Oxygen Sensor Accuracy; Alarms
- Software verification and validation
- Electrical / EMC / RFID including battery charge and discharge
- Biocompatibility
- ISO 18562-2:2017 - Particulate matter
- ISO 18562-3:2017 - Volatile organic compounds

The device met all requirements.

VIII Discussion of Differences

The subject device and the predicate device have been found to be substantially equivalent. All devices have a similar fundamental scientific technology, operating system, components and principle of operation. All are indicated for home, institution, and travel/mobile environments outside the home.

The major technical differences between the Inogen Rove 6 and the predicate device, Inogen Rove 4, are:

- The Inogen Rove 4 with a 8-cell battery measures 7.6”H, 2.9”W, 7.3”D. The Inogen Rove 6 with a 8-cell battery measures 8.1”H, 3.3”W, 7.2”D. The Inogen Rove 6 is slightly larger in size.
- The Inogen Rove 6 provides two additional dose settings, offering an overall maximum dose of oxygen at 1260 ml/min as compared to the maximum of 840 ml/min from the Inogen Rove 4. The higher maximum output of the Rove 6 device remains below the maximum level of other cleared portable oxygen concentrators (see similarities with the Reference device below).
- The Maximum Outlet Pressure claimed for Inogen Rove 6 is < 28.9 PSI, whereas the Rove 4 is <22 PSI. The Inogen Rove 6 Maximum Outlet Pressure is claimed at a level similar to the previously cleared Invacare Platinum Mobile Oxygen Concentrator (K160630) with a maximum outlet pressure of <28.5 PSI. Both maintain outlet pressures below that of compressed gas. Test results for the Rove 6 demonstrate actual outlet pressures in the range of 24-25 PSI.

The similarities between the Reference Device, Oxus GCE Zen-O (K162433), and the Rove 6 confirms as the scientific basis the additional settings and higher output of the Rove 6 (as compared to the Rove 4 major technical differences) are still within a safe range and do not raise different questions of safety and effectiveness.

- The Oxus GCE Zen-O measures 12.3”H x 8.3”W x 6.6”D and weighs 10.25 lbs. The Inogen Rove 6 with a 8-cell battery measures 8.1”H, 3.3”W, 7.2”D and weighs 4.8 lbs. The Inogen Rove 6 is smaller in size and weight.
- Both devices offer six (6) settings, but the Inogen Rove 6 delivers a set output per minute (ml/min) whereas the Zen-O delivers a set output per breath (ml/breath). When comparing the total output per minute, the maximum output from the Inogen Rove 6 (1260 ml/min) is similar to the Zen-O setting 6 at 20 breaths/min, (20 breath/min x 66ml/min = 1320 ml/min). Zen-O highest output is setting 6 at 35 breath/min, totaling 2310 mil/min.

IX Substantial Equivalence Conclusion

The subject device and the predicate device have been found to be substantially equivalent. Both devices have a similar fundamental scientific technology, operating system, components, and principle of operation. Both are indicated for home, institution, and travel/mobile environments outside the home.

The Inogen Rove 6 and the Inogen Rove 4 meet safety and performance standards required for portable oxygen concentrators verified through testing at a nationally registered test laboratory. The differences noted between the subject and predicate devices do not raise any additional concerns regarding safety or effectiveness.