December 9, 2022

Inogen
Sandra Leclair
Regulatory Affairs Specialist, IV
301 Coromar Drive
Goleta, California 93117

Re: K222086
Trade/Device Name: Inogen Rove 4 Portable Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: November 9, 2022
Received: November 9, 2022

Dear Sandra Leclair:

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 on last page.

510(k) Number *(if known)*

K222086

Device Name

Inogen Rove™ 4 Portable Oxygen Concentrator Portable Oxygen Concentrator

Indications for Use *(Describe)*

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.

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.

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

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Date Prepared: 9-Dec-22

I Sponsor:

Inogen, Inc.
301 Coromar Drive
Goleta, California 93117

Sponsor Contact: Sandy LeClair
Regulatory Affairs Specialist, IV
sleclair@inogen.net
Phone: 315-868-1202

II Device

Proprietary or Trade Name: Inogen Rove 4 Portable Oxygen Concentrator
Common/Usual Name: Generator, Oxygen, Portable
Regulation Number: 868.5440
Product Code: CAW

III Predicate Device:

Proprietary or Trade Name: X-PLO$_2$R, K203086
Common/Usual Name: Generator, Oxygen, Portable
Regulation Number: 868.5440
Product Code: CAW

IV Device Description:

The Inogen Rove™ 4 Portable Oxygen Concentrator is a 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 and transport modalities. It is used with a nasal cannula to deliver oxygen from the device to the patient. This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.

The Inogen Rove 4 Portable Oxygen Concentrator is capable of continuous use in a home, institution, 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 cord.

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, valves, sensors, and software are used to control the cycle to make the system function.

Oxygen is delivered to the patient on a pulse dose basis in pre-set 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 4 Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas.

The Inogen Rove 4 Portable Oxygen Concentrator utilizes Bluetooth technology that pairs the portable oxygen concentrator to a mobile device or tablet using the Inogen Connect App.

The basic technology of the Inogen Rove 4 Portable Oxygen Concentrator is equivalent to other cleared oxygen concentrators. The principles of operation are equivalent to the predicate device noted above: X-PLO$_2$R, K203086.

Specifications:	
Dimensions:	
With 4-cell battery	6 x 2.7 x 7.5 in (15.1 x 6.9 x 19.1 cm)
With 8-cell battery	6 x 2.7 x 7.8 in (15.1 x 6.9 x 19.7 cm)
Weight:	
With 4-cell battery	3.0 pounds (1.4kg)
With 8-cell battery	3.3 pounds (1.5kg)
Nominal sound level	39 dBA at setting 2 (MDS-Hi) Maximum system sound power of 59 dBA Maximum system sound pressure of 51 dBA Typical alarm sound pressure of 57 dBA
Mains Isolation	Remove both the DC input cord from device as well as the battery pack.
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
Maximum outlet pressure	<22 PSI 18.7 PSI (129 kPa) $\pm$10%
AC Power	100 to 240 VAC, 50 to 60 Hz Autosensing 2.0 – 1.0A
DC Power	13.5-15.0 VDC, 100W Max voltage: 12.0 to 16.8 VDC ($\pm$ 0.5)
Battery type	Lithium Ion
Rechargeable battery:	12.0 to 16.8 VDC ($\pm$ 0.5)
Battery re-charge time	4-cell (BA-404): up to 3 hours 8-cell (BA-408): 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	5% to 95%, non-condensing Store in a dry environment.
Measurement uncertainties:	Flow rates: $\pm$ 2% of reading Pulse volumes: $\pm$3% of reading or 3ml (whichever is greater) Pressure: $\pm$ 0.03 psig (General)/$\pm$0.05 cm H2O (Inspiratory Trigger Sensitivity) Oxygen concentration: $\pm$0.4% (not accounting for temperature, barometric pressure, and time from measurement device calibration)

*Based on atmospheric pressure of 14.7 psi (101 kPa) at 70°F (21°C)

** 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 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.

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 4 User Interface elements with respect to the predicate device, the Belluscura X-PLOR. The user interface features are broken down by category and the elements of each category.

All Inogen Rove 4 User Interface elements have been found to be substantially equivalent to that of the Belluscura X-PLOR.

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

	Predicate Device: Belluscura X-PLO$_2$R	**Subject Device: Inogen Rove 4**	**Comparison**
510K#	K203086	K222086	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 X-PLO2R is a transportable, software-monitored device designed to be used by patients as a portable oxygen delivery system requiring high concentrations of oxygen on a supplemental basis. It is small, portable, and is capable of continuous use in home, institutional, and travel/ mobile environments. This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.	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.	Substantially equivalent The predicate device and subject device provide supplemental oxygen to patients prescribed respiratory therapy.
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 patient only	Adult patient only	Substantially equivalent
User/Patient Interface	User interface panel	User interface panel	Substantially equivalent
	LCD Display to convey information about operating status in numbers, text, 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 “Alarm/Warning” triangle symbol on LCD display is 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. Both the Inogen Rove 4 and Belluscura X-PLOR use “Alarm/Warning” triangle symbol to indicated alarm function.
	Breath Detect Notification – breath detect icon pops up on the LCD display 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. Both the Inogen Rove 4 and Belluscura X-PLOR have an indicator for when a breath has been detected

	Predicate Device: Belluscura X-PLO$_2$R	Subject Device: Inogen Rove 4	Comparison
			and a pulse of oxygen has been delivered.
	Auditory Buzzer – Audible beeps are emitted to indicate alarm or status change conditions in compliance with ISO 60601-1-8.	Auditory Buzzer – Audible beeps are emitted to indicate alarm or status change conditions in compliance with ISO 60601-1-8.	Substantially equivalent.
	Sieve beds – Sieve beds are user replaceable by using the cartridge pull handle to pull the cartridge assembly out of the POC. Then, push in the new replacement all the way into the unit so the handle lays flat.	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.	Substantially Equivalent. Both the Inogen Rove 4 and Belluscura X-PLOR allow Sieve Beds to be user replaceable. The Inogen Rove 4 are replaced with the aid of a common household tool, an Allen key, while the Belluscura X-PLOR utilizes a pull tab.
	Air Intake Filter - Patient instructed to clean the air intake filter once per week.	Particle Filter – Patient instructed to clean particle filters once per week.	Substantially equivalent.
	Optional accessories - Carry Bag, Strap, Backpack, External Battery Charger	Optional accessories - Carry Bag, Backpack, External Battery Charger	Substantially equivalent.
	No Mobile Application	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. The Inogen Rove 4 allows concentrator information to be viewed on a mobile device as well as on the concentrator display. The same information is available on the Belluscura X-PLOR concentrator display only.
Operating System	Software monitored	Software monitored	Substantially Equivalent
Bluetooth Technology	No 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.	Substantially Equivalent The Inogen Rove 4 allows concentrator information to be viewed on a mobile device as well as on the concentrator display. The same information is

	Predicate Device: Belluscura X-PLO$_2$R	Subject Device: Inogen Rove 4	Comparison
			available on the Belluscura X-PLOR 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 - Off the shelf 7’ nasal cannula	Cannula – Is user supplied off-the-shelf	Substantially equivalent.
	Battery – utilizes a 4 or 8-cell lithium battery. To attach the battery, slide it on to the base of the concentrator until the latch is in the locked position.	Battery – utilizes a 4 or 8-cell lithium battery. To attach the battery, slide it on to the base of the concentrator.	Substantially equivalent.
Size	With 4-cell battery: 7.0”H, 7.3” W, 2.9”D	With 4-cell battery: 7.5”H, 6.0” W, 2.7” D	Similar: Inogen is smaller
Principle of Operation	The Belluscura X-PLO2R Portable Oxygen Concentrator (POC) utilizes Pressure Swing Adsorption (PSA) technology to produce 82 to 92% oxygen and deliver it to patients though a standard, single-lumen nasal cannula on a pulse dose basis. The alternate filling and purging of these tubes is known as PSA. Oxygen in the reservoir tank is then delivered to the patient when an inhalation is detected. An electronically controlled manifold opens the delivery valve for a defined amount of time depending on the measured breath rate and flow setting to ensure the patient is receiving the bolus volume defined for that flow setting.	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 by pressure through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. Oxygen is collected in an accumulator reservoir. The airflow is then changed, and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Waste nitrogen is exhausted back into the room. A series of sieve beds, a manifold with precision valves, sensors, and embedded software to control the cycle are used to make the system function. Oxygen is delivered to the patient on a demand flow basis 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™ 4 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 onto the patient. Pressure sensors and embedded software are used to control the conserving function.	Substantially equivalent.

<table>
<tr><th></th><th>Predicate Device: Belluscura X-PLO$_2$R</th><th>Subject Device: Inogen Rove 4</th><th>Comparison</th></tr>
<tr><td>Operating Conditions</td><td>Portable. For use in home institutional, and travel or mobile environments.</td><td>Portable. For use in home, institution and transport modalities.</td><td>Substantially equivalent.</td></tr>
<tr><td colspan="4">Performance</td></tr>
<tr><td>Oxygen Delivery Mode</td><td>Pulse Dose</td><td>Pulse Dose</td><td>Substantially equivalent.</td></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>15</td><td>14</td><td>27</td><td>40</td><td>53</td></tr>
<tr><td>20</td><td>10</td><td>20</td><td>30</td><td>40</td></tr>
<tr><td>25</td><td>8</td><td>16</td><td>24</td><td>32</td></tr>
<tr><td>30</td><td>7</td><td>14</td><td>20</td><td>27</td></tr>
<tr><td>35</td><td>6</td><td>12</td><td>17</td><td>23</td></tr>
<tr><td>40</td><td>5</td><td>10</td><td>15</td><td>20</td></tr>
<tr><td>TOTAL VOLUME PER MINUTE (ml/min)</td><td>200</td><td>400</td><td>600</td><td>800</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></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>Similar volumes. Inogen has higher volumes per minute for each setting.</td></tr>
<tr><td>Oxygen Purity</td><td>82% to 92% at all settings</td><td>87% to 96% at all settings</td><td>Similar. Inogen has higher oxygen concentrations per minute for each setting.</td></tr>
<tr><td>Maximum Outlet Pressure</td><td>10psig (41.37 kPa)</td><td>< 22 PSI
18.7 PSI (129 kPa) ± 10%</td><td>Inogen has a higher maximum outlet pressure. Difference discussed further in section VIII Discussion of Differences.</td></tr>
<tr><td colspan="4">Performance standards</td></tr>
<tr><td>Performance and Electrical Safety and EMC</td><td>• IEC 60601-1
• IEC 60601-1-2
• IEC 60601-1-6
• IEC 60601-1-8
• IEC 60601-1-11
• ISO 80601-2-69</td><td>• IEC 60601-1:2012
• IEC 60601-1-2: 2020
• IEC 60601-1-6:2020
• IEC 60601-1-8:2012
• IEC 60601-1-11:2015
• ISO 80601-2-69:2020</td><td>Similar</td></tr>
</table>

	Predicate Device: Belluscura X-PLO$_2$R	Subject Device: Inogen Rove 4	Comparison
	• ISO 80601-2-67 • IEC 62366-1	• ISO 80601-2-67:2020 • 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 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 a 4 or 8-cell lithium battery.	Substantially equivalent
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

VII Substantial Equivalence Discussion

Intended Use/ Indications for Use

The Inogen Rove 4 and the Belluscura X-PLO$_2$R 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 and transport environments. Both devices are to be used as an oxygen supplement and is not intended to be life sustaining or life supporting. Inogen has included this statement as part of the Intended Use/Indications for Use statement.

Technological Characteristics and Principles of Operation

The Inogen Rove 4 and the Belluscura X-PLO$_2$R both operate on Pressure Swing Adsorption (PSA) technology to produce oxygen and deliver it to patient via a standard oxygen 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. 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 major technical differences between the Inogen Rove™ 4 and the predicate device, Belluscura X-PLO$_2$R are:

- The Belluscura X-PLO$_2$R with a 4-cell battery measures 7.0”H, 7.3”W, 2.9”D. The Inogen Rove 4 with a 4-cell battery measures 7.5”H, 6.0”W, 2.7”D. The Inogen Rove™ 4 is smaller in size.
- The Beluscura X-PLO$_2$R with a 4-cell battery claims a battery duration of up to 2.5 hours, the Inogen Rove 4 with a 4-cell battery has a duration of 4:57 hours.
- The Belluscura X-PLO$_2$R does not have a mobile application. The Inogen Rove™ 4 has a

Inogen Connect Mobile Application – Optional mobile application for viewing device settings, battery information, and current alerts, available for iOS and Android in English, French allows concentrator The Inogen Rove™ 4 allows information to be viewed on a mobile device as well as on the concentrator display. The same information is available on the Belluscura X-PLO$_2$R concentrator display only.

- The Belluscura X-PLO$_2$R does not have Bluetooth technology. Inogen Rove 4 features Bluetooth technology using the Inogen Connect App – BLE Connection to Android or iPhone.

- The Maximum Outlet Pressure for Inogen Rove 4 is < 22 PSI, 18.7 PSI (129 kPa) ± 10% whereas the Belluscura X-PLO$_2$R is 10psig (41.37 kPa). The Inogen Rove 4 Maximum Outlet Pressure is similar to previously cleared portable oxygen concentrators:
    - Respironics SimplyGo Portable Oxygen Concentrator, K111885, Maximum Outlet Pressure of 20 psig
    - GCE Zen-O Portable Oxygen Concentrator, K162433, Maximum Outlet Pressure of 20.5 psi

- The Inogen Rove 4 and the Belluscura X-PLO$_2$R both 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.

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.