December 22, 2025

Shenzhen Homed Medical Device Co., Ltd.
Shengming Shi
Regulatory Affairs Manager
Room 1601-1604, A Building, Jinxiu III, No. 85 Hudi Pai
Songxuan Community, Guanhu Street, Longhua District
Shenzhen, Guangdong 518000
China

Re: K252616
Trade/Device Name: Portable oxygen concentrator (JLO-190P)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW,
Dated: November 28, 2025
Received: November 28, 2025

Dear Shengming Shi:

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,

JAMES J. LEE -S

for 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252616

Please provide the device trade name(s).

Portable oxygen concentrator (JLO-190P)

Please provide your Indications for Use below.

The Portable Oxygen Concentrator(JLO-19P) provides a high concentration of oxygen to patients requiring supplemental oxygen. 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1. Sponsor

Sponsor's Name:	Shenzhen Homed Medical Device Co., Ltd.
Contact Person:	Shi Shengming
Address:	Room 1601-1604, A Building, Jinxiu III, No. 85 Hudi Pai, Songxuan Community, Guanhu Street, Longhua District, Shenzhen City, Guangdong, China
Telephone:	+86-755-29821671
Fax number:	+86-755-29821673
E-mail:	shifei@homedgroup.com
Date prepared:	November 28th, 2025

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Portable oxygen concentrator
Classification name:	Generator, Oxygen, Portable
Classification:	II
Review Panel:	Anesthesiology
Product Code:	CAW
Regulation Number:	868.5440

3. Predicate Device Information

Trade Name:	Inogen Rove 6 Portable Oxygen Concentrator	FreeStyle® Comfort® Oxygen Concentrator
510(k) Number:	K230052	K250671
Classification name:	Generator, Oxygen, Portable	Generator, Oxygen, Portable
Classification:	II	II
Review Panel:	Anesthesiology	Anesthesiology
Product code:	CAW	CAW
Regulation No.:	868.5440	868.5440

4. Device Descriptions

The Portable Oxygen Concentrator JLO-190P is a device that uses the principle of molecular sieve pressure swing adsorption to increase oxygen concentration by adsorption of nitrogen and other gas components. The device needs to be used with a nasal oxygen cannula, which can provide oxygen supplementation to the user.

This product adopts the induction pulse mode to deliver oxygen. The induction pulse mode relies on the sensitive probe inside the machine to detect your breathing and deliver oxygen according to your breathing frequency. It monitors your breathing rate and delivers oxygen when you breathe in and stops when you breathe out.

Portable oxygen concentrator consists of air compressor, molecular sieve adsorption tower, oxygen storage tank, control system, alarm system, accessories (nasal oxygen cannula, lithium battery pack).

5. Intended Use and Indications for Use

The Portable Oxygen Concentrator (JLO-19P) provides a high concentration of oxygen to patients requiring supplemental oxygen. It may be used in home, institution, 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.

6. Substantial Equivalent Comparisons

Model of Inogen Rove 6 manufactured by Inogen Inc and model of FreeStyle Comfort Oxygen Concentrator (AS200/FreeStyle Comfort) manufactured by CAIRE Inc are selected for equivalent comparisons. See the following table for details of comparisons.

Items	Subject device (JLO-190P)	Predicate Device (Inogen Rove 6, K230052)	Reference Device (FreeStyle Comfort, K250671)	Remark
Classification Name	Generator, Oxygen, Portable	Generator, Oxygen, Portable	Generator, Oxygen, Portable	Substantial Equivalence
Product Code	CAW	CAW	CAW	Substantial Equivalence
Regulation Number	21 CFR 868.5440	21 CFR 868.5440	21 CFR 868.5440	Substantial Equivalence
Classification Type	Class II	Class II	Class II	Substantial Equivalence
Intended use/ Indication for Use	The Portable Oxygen Concentrator (JLO-190P) provides a high concentration of oxygen to patients requiring supplemental oxygen. It may be used in home, institution, 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 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.	The FreeStyle Comfort Oxygen Concentrator can deliver concentrated oxygen with either a fixed-minute pulse delivery or can be set to operate using autoSAT pulse delivery. The FreeStyle Comfort is used on a prescriptive basis by patients requiring supplemental oxygen to increase blood oxygen saturation. FreeStyle Comfort may be used in the home, institution, and transport modes. The device is not intended for life support, nor does it provide any patient monitoring capabilities.	Substantial Equivalence Different expression, same meaning
Intended patient	Adult	Adult	Adult	Substantial Equivalence
Intended environment	Home, institution, and transport modalities	Home, institution, and transport modalities	Home, institution, and transport modes	Substantial Equivalence
Prescriptive	Yes	Yes	Yes	Substantial Equivalence
Technology	Prescriptive Pressure Swing Adsorption with molecular sieve	Prescriptive Pressure Swing Adsorption with molecular sieve	Prescriptive Pressure Swing Adsorption with molecular sieve	Substantial Equivalence

<table>
<tr><td>Dimensions</td><td>185 length x 90 width x 210 height (mm)
18.5 length x 9 width x 21 height (cm)</td><td>With standard battery: 7.2 x 3.3 x 8.1 in (18.2 x 8.3 x 20.7 cm)</td><td>With Single Battery:10.0 x 7.3 x 3.1 in (25.4 x 18.5 x 7.9 cm)
With Double Battery:11.0 x 7.3 x 3.1 in (27.9 x 18.5 x 7.9 cm)</td><td>Substantial Equivalence</td></tr>
<tr><td>Weight</td><td>2.12kg (with batteries)</td><td>With standard battery: 4.8 pounds (2.2kg)</td><td>With standard battery pack: 5 lbs (2.3 kg)
With double battery pack: 6 lbs (2.7 kg)</td><td>Substantial Equivalence</td></tr>
<tr><td>Oxygen Concentration</td><td>93%±3%</td><td>90% - 3%/+6% at all settings</td><td>90% (+5.5% / -3%)</td><td>Substantial Equivalence</td></tr>
<tr><td>Inspiratory trigger sensitivity</td><td><0.4 cmH_2O (<39.2 Pa)
(expressed in positive pressure)</td><td><0.12 cmH_2O
(expressed in positive pressure)</td><td>>-0.1 cm H_2O, a maximum adjustable range of -0.3 to -0.40 cm H_2O, (expressed in negative pressure)</td><td>Substantial Equivalence</td></tr>
<tr><td>Output pressure</td><td>≤26.1Psi (180kPa)</td><td>< 28.9 PSI (199 kPa)</td><td><30 PSI</td><td>Substantial Equivalence</td></tr>
<tr><td>Oxygen output flow (pulse mode)</td><td>
<table>
<tr><td>Gear setting</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td></tr>
<tr><td>Respiratory rate times/min</td><td colspan="6">Average pulse volume (mL)</td></tr>
<tr><td>10</td><td>21mL</td><td>42mL</td><td>63mL</td><td>80mL</td><td>100mL</td><td>120mL</td></tr>
<tr><td>15</td><td>14mL</td><td>28mL</td><td>42mL</td><td>56mL</td><td>70mL</td><td>84mL</td></tr>
<tr><td>20</td><td>11mL</td><td>21mL</td><td>32mL</td><td>42mL</td><td>53mL</td><td>63mL</td></tr>
<tr><td>25</td><td>8mL</td><td>17mL</td><td>25mL</td><td>34mL</td><td>42mL</td><td>50mL</td></tr>
<tr><td>30</td><td>7mL</td><td>14mL</td><td>21mL</td><td>28mL</td><td>35mL</td><td>42mL</td></tr>
<tr><td>35</td><td>6mL</td><td>12mL</td><td>18mL</td><td>24mL</td><td>30mL</td><td>36mL</td></tr>
<tr><td>40</td><td>5mL</td><td>1lmL</td><td>16mL</td><td>21mL</td><td>26mL</td><td>32mL</td></tr>
<tr><td colspan="7">mL/breath, Deviation positive and negative 15% (Uncertainty of ±5%), refer to ISO 80601-2-67</td></tr>
<tr><td>Total flow per minute (mL/min)</td><td>210</td><td>420</td><td>630</td><td>800</td><td>1000</td><td>1200</td></tr>
</table>
<table>
<tr><td>BREATHS PER MINUTE</td><td>Setting 1</td><td>Setting 2</td><td>Setting 3</td><td>Setting 4</td><td>Setting 5</td><td>Setting 6</td></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>
<table>
<tr><td>Breath Rate</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</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></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></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></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></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></tr>
<tr><td>40</td><td>5.3</td><td>10.5</td><td>15.8</td><td>21.0</td><td>26.3</td></tr>
<tr><td>Total Volume Per Min (mL/min)</td><td>210</td><td>420</td><td>630</td><td>840</td><td>1050</td></tr>
</table>
</td><td>Substantial Equivalence</td></tr>
<tr><td>Filters</td><td>Air Inlet Filter</td><td>Air Inlet Filter</td><td>Air Inlet Filter</td><td>Substantial Equivalence</td></tr>
<tr><td>Power Supply</td><td>AC Power Adaptor: Input: a.c. 100-240V, 50/60Hz, 2.0A; Output: 19Vd.c., 6.31A
Battery (Lithium Ion): 14.6Vd.c., 6000mAh</td><td>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 (Lithium Ion): 12.0 to 16.8 VDC (+ 0.5)</td><td>AC power: 100-240 VAC, 50-60Hz, 120W Max; DC power:11-18 VDC (10 max amp)
Battery - Utilizes a Lithium-Ion Battery Pack (8 cell) or Optional Double Battery (16 cell)</td><td>Substantial Equivalence</td></tr>
<tr><td>Acoustic Noise</td><td>48dB(A) @ setting 2</td><td>39 dBA at setting 2 (MDS-Hi)</td><td>Max 43.0 dB(A) @ 2</td><td>Substantial Equivalence</td></tr>
<tr><td>Breath Detect Notification</td><td>Green LED illuminates when a breath is detected, and an oxygen pulse is triggered</td><td>Green LED on UIP illuminates when a breath is detected, and an oxygen pulse is triggered</td><td>Green LED on LCD, Display illuminates when a breath is detected, and an oxygen pulse is triggered</td><td>Substantial Equivalence</td></tr>
</table>

Alarm function	Once alarming conditions trigger, the current fault code will be displayed on the display screen, and an alarm will sound. The alarming functions conform to 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. -Auditory Speaker - Audible beeps are emitted to indicate alarm or status change conditions in compliance with ISO 60601-1-8.	Alarm Indicator – yellow “Alarm/Warning” triangle symbol on LCD display is to indicate abnormal operating 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.	Substantial Equivalence
User/Patient Interface	User interface panel, Nasal cannula, Particle filter, Alarm Indicator, Alarm Indicator speaker 2.8-inch color display to convey information about operating status in numbers, text, and symbols.	User interface panel, Nasal cannula, Particle filter, Alarm Indicator, Alarm Indicator speaker LCD Display to convey information about operating status in numbers and symbols. Bluetooth, APP	User interface panel, Nasal cannula, Particle filter, Alarm Indicator, Alarm Indicator buzzer LCD Display to convey information about operating status in numbers, text, and symbols. Bluetooth, APP	Substantial Equivalence
Operating Environment, Maintenance	Temperature: 5 to 40˚C (41 to 104°F) Humidity: ≤80 % (non-condensing) Altitude: 0 to 10,000 ft (0 to 3048 meters)	Temperature: 41 to 104°F (5 to 40°C) Humidity 15% to 90%, non-condensing Altitude: 0 to 10,000 ft (0 to 3048 meters)	Temperature: 41°F to 104°F (5°C to 40°C) Humidity:15 - 95% relative humidity (non-condensing) Altitude: -1250 to 10,000 ft (-381 to 3048 m)	Substantial Equivalence
Shipping & Storage, Environment	Temperature: -25 ~ 70℃ (-13 to 158°F) Humidity: 0 -90% (non-condensing) Store in a dry environment	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.	Temperature: -13°F to + 158°F (-25°C to +70°C) up to 10000 ft (3048 m) Humidity:0 - 90% non-condensing	Substantial Equivalence

Principle of Operation	Portable oxygen concentrator refers to a device that uses the molecular sieve pressure swing adsorption principle to increase the oxygen concentration by absorbing nitrogen and other gas components. When the device is working, compressed air is injected into a closed adsorption tower equipped with a molecular sieve, causing the pressure in the adsorption tower to increase. The molecular sieve absorbs a large amount of nitrogen in the compressed air as the ambient pressure increases, while the oxygen in the compressed air still exists in the form of gas and is collected through a certain pipeline. This process is usually called the "adsorption" process. When the molecular sieve in the container adsorbs nitrogen to the critical state of adsorption saturation, the adsorption tower is blown to reduce the pressure. As the ambient pressure decreases, the molecular sieve's ability to adsorb nitrogen decreases, and the nitrogen is released from the inside of the molecular sieve and discharged as waste gas. This process is usually called "desorption". This product uses the induction pulse mode to deliver oxygen. The induction pulse mode relies on the sensitive probe inside the machine to detect your breathing and deliver oxygen according to your breathing rate. It monitors your breathing rate, supplies oxygen when you inhale air, and stops supplying oxygen when you exhale air.	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.	The control board uses software to operate the unit. The device operating principle is a process known as Pressure Swing Adsorption, or PSA. Air is drawn into the device through the air intakes to the air compressor. Pressurized air flows from the air compressor to each of the (molecular) sieve beds in cycles. As one sieve bed is filled with pressurized air, the oxygen passes through the sieve bed. As the oxygen travels through the sieve bed, the nitrogen molecules collect on the molecular sieve. At the end of the cycle, the nitrogen is purged using enriched oxygen, then the process begins again with the alternate sieve bed (one sieve bed depressurizes while the other sieve bed is pressurized). This process continuously repeats from one sieve bed to the other, producing highly concentrated oxygen. Concentrated oxygen flows from the sieve beds to the product tank, then through sensors that measures both oxygen concentration and flow, then delivered to the patient.	Substantial Equivalence Both use pressure swing adsorption with molecular sieve.

Device Components	Oxygen generator host, AC/DC Power Adapter, Power cord, Molecular sieve, Battery, Battery button, Nasal cannula	Oxygen generator, AC/DC Power Adapter, DC Power Cable, Molecular sieve, Battery, Battery release latch, Cannula	Oxygen generator, AC/DC Power Adapter, DC Power Cable, Molecular sieve, Rechargeable single or double battery, Cannula	Substantial Equivalence
Material of Patient contacting	Outer enclosure: PC+ABS	Not publicly available	Outer enclosure: PC/ABS	Substantial Equivalence
Biocompatibility	ISO 10993-1 ISO 18562-1	ISO 10993-1 ISO 18562-1	ISO 10993-1 ISO 18562-1	Substantial Equivalence
Performance and Electrical Safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-8 IEC 60601-1-11 ISO 80601-2-69 ISO 80601-2-67	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-8 IEC 60601-1-11 ISO 80601-2-69 ISO 80601-2-67	IEC 60601-1:2012+AMD1:2020 IEC 60601-1-2:2015+A1:2021 Ed.4.1 IEC 60601-1-8:2020 IEC 60601-1-11:2020 ISO 80601-2-69:2020 Ed. 2 ISO 80601-2-67:2020 Ed. 2	Substantial Equivalence

The subject Portable Oxygen Concentrator (JLO-190P) and Inogen Rove 6 Portable Oxygen Concentrator(predicate) and FreeStyle Comfort Oxygen Concentrator (Referenced) are similar in intended purpose, main functions, scientific technology and operation principle. Although there are differences in design between Portable Oxygen Concentrator (JLO-190P) and predicate product (K230052 and K250671), but the subject device meets the design requirements and international standards, these differences will not raise any new safety and effectiveness issues on clinical use.

7. Discussion of Non-Clinical Tests

7.1 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject device model JLO-190P.

-IEC 60601-1: 2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

-IEC 60601-1-2: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

-IEC 60601-1-8: 2020 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: 2020 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

-ISO 80601-2-67: 2020 Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen concentrator equipment

-ISO 80601-2-69: 2020 Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment

7.2 Software Verification and Validation Testing

Software verification and validation was performed for the subject device in accordance with the following standard and guidance.

-IEC62304:2015 Medical device software - Software life cycle processes

-FDA software guidance: Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff

7.3 Performance test

Performance testing was performed on the subject device to FDA recognized consensus standards for basic safety and essential performance. The testing includes:

*Pulse volume
*Pressure monitoring
*Oxygen Purity under various conditions
*Inspiratory trigger sensitivity (trigger pressure)
*Alarms
*Power management

7.4 Biocompatibility Testing

Biocompatibility tests were conducted on the subject device model JLO-190P. The devive complies with the biocompatibility endpoints of ISO 10993 series, and the breathing gas pathway conforms to the ISO18562 series. The battery of testing was performed to the following FDA recognized consensus standards:

-ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

-ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity

-ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

-ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation

-ISO 18562-1:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process

-ISO 18562-2:2024 Tests for emissions of volatile Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter

-ISO 18562-3:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Test for emissions of volatile organic compounds (VOCs)

8. Clinical Testing

Substantial equivalence does not depend on clinical test data.

9. Conclusions

From the substantial equivalent comparisons and the results of non-clinical testing data, it concludes that the subject device is substantially equivalent to the predicate device.