December 16, 2025

Shenzhen HarveyMed Technology Co., Ltd.
% James Tsai
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K252268
Trade/Device Name: V series portable oxygen concentrator (V5, V5C, V6, V6C)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: November 17, 2025
Received: November 17, 2025

Dear James Tsai:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic.

See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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.	K252268

Please provide the device trade name(s).

V series portable oxygen concentrator (V5, V5C, V6, V6C)

Please provide your Indications for Use below.

The V series Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis in a home, institutional, or travel environment. The device is not intended for life support, nor does it provide any patient monitoring capabilities.

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. Contact details

1.1 Applicant information

Applicant Name	Shenzhen HarveyMed Technology Co., Ltd.
Address	B203 Weike science and technology building, No. 20, Gaoxin West Road, Dongzhou community, Guangming Street Guangming District, Shenzhen, Guangdong, China
Phone No.	+86-755-27900675
Contact person	Huang Zhi'ang
E-mail	zhiang.huang@harveymed.com
Date Prepared	November 14th, 2025

1.2 Submission Correspondent

Company	Shenzhen Joyantech Consulting Co., Ltd.
Address	1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong, 518000, China
Phone No.	+86-755-86069197
Contact person	James Tsai
E-mail	james_tsai@cefda.com; zhiang.huang@harveymed.com
Website	http://www.cefda.com

2. Device information

2.1 Subject device

Trade name	V series portable oxygen concentrator
Model	V5, V5C, V6, V6C
Classification	II
Classification name	Portable Oxygen Generator
Product code	CAW
Regulation No.	868.5440

2.2 Primary predicate device

Trade Name	Inogen Rove 6 Portable Oxygen Concentrator
510(k) Number	K230052
Sponsor	Inogen, Inc.
Classification	II
Classification name	Portable Oxygen Generator
Product code	CAW
Regulation No.	868.5440

2.3 Secondary predicate device

Trade Name	Portable Oxygen Concentrator (Model: P2-TOC)
510(k) Number	K242718
Sponsor	Qingdao Kingon Medical Science and Technology Co., Ltd.
Classification	II
Classification name	Portable Oxygen Generator

Product code	CAW
Regulation No.	868.5440

3. Device Description

The V series Portable Oxygen Concentrator is intended to release oxygen for respiratory therapy by means of molecular sieve/pressure swing adsorption technology. The machine utilizes the physical principle of pressure swing adsorption with a molecular sieve to adsorb nitrogen and other gas components Device to increase oxygen concentration. It supplies a pulsed high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The V series devices are small, portable and may be used in home, institutional, or travel environment.

The V series Portable Oxygen Concentrator has both pulse mode and continuous mode, there are 6 level/gear settings for pulse mode, and 1 level/gear setting for continuous mode, see the descriptions in the table below:

Gear Settings	Level 1 (Gear 1)	Level 2 (Gear 2)	Level 3 (Gear 3)	Level 4 (Gear 4)	Level 5 (Gear 5)	Level 6 (Gear 6)	Mode C
Rated Flow Rate	210 mL/min	420 mL/min	630 mL/min	840 mL/min	1000 mL/min	1200 mL/min	1.2 L/min

The 4 models have the same appearances, intended use, technical characteristics, and working principle, only a difference in gear setting, that is, the 4 models differ in the firmware/software, see the description in table below:

Models	Level/Gear setting						
	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6	Mode C
V5	●	●	●	●	●	/	/
V5C	●	●	●	●	●	/	●
V6	●	●	●	●	●	●	/
V6C	●	●	●	●	●	●	●
“●” means “standard configuration”; “/” means “do not have the configuration”							

4. Intended Use/Indication for Use

The V series Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis in a home, institutional, or travel environment. The device is not intended for life support, nor does it provide any patient monitoring capabilities.

5. Substantial Equivalence Comparison

The subject device and predicate devices have the same intended use and the following similarities:

- Same Indications for Use.
- Same operating principle.
- Similar technological characteristics.

See the comparison information in details in the table below.

Item	HarveyMed V series (Proposed device)	Inogen Rove 6 Portable Oxygen Concentrator, K230052 (Primary predicate device)	Kingon, P2-TOC, K242718 (Secondary predicate device)	Comparisons
Regulation number	21 CFR 868.5440	21 CFR 868.5440	21 CFR 868.5440	Substantial equivalence
Classification	Class II	Class II	Class II	Substantial equivalence
Product Code	CAW	CAW	CAW	Substantial equivalence
Intended use/Indications for use	The V series Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis in a home, institutional, or travel environment. The device is not intended for life support, nor does it provide any patient monitoring capabilities.	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.	The Portable Oxygen Concentrator P2-TOC is intended to provide supplemental low flow oxygen. The device is not intended for life support, nor does it provide any patient monitoring capabilities.	Substantial equivalence
Environment of Use	Home, institutional, or travel environment	Home, institutional, or travel modalities	Home, outside the home	Substantial equivalence
Intended patient	1. Adult 2. Patients requiring supplemental oxygen	1. Adult 2. Patients requiring supplemental oxygen	1. Adult 2. Patients requiring supplemental oxygen	Substantial equivalence
Prescriptive	Yes	Yes	Yes	Substantial equivalence
Scientific technology/Principle of operation	1. Breath detection technology. 2. Molecular Sieve/pressure swing adsorption technology.	1. Breath detection technology. 2. Molecular Sieve/pressure swing adsorption technology.	1. Breath detection technology. 2. Pressure Swing Adsorption with molecular sieve.	Substantial equivalence

Item	HarveyMed V series (Proposed device)	Inogen Rove 6 Portable Oxygen Concentrator, K230052 (Primary predicate device)	Kingon, P2-TOC, K242718 (Secondary predicate device)	Comparisons
User/patient interface	-Buttons -LCD Display -Nasal cannula -Sieve beds -Particle filter -Alarm Indicator -Auditory Speaker	-LCD display -Alarm Indicator -Breath detect notification -Auditory Speaker -Battery release latch -Sieve beds -Particle filter	-Buttons -LCD Display -Nasal cannula -Sieve beds -Particle filter -Alarm Indicator -Auditory Speaker	Substantial equivalence
Components	-Oxygen concentrator -AC adapter -DC connector -Nasal cannula -Battery -Shoulder bag	-Oxygen concentrator -AC/DC power adapter -DC power cable -Cannula -Battery -Carry Bag, Backpack, Cart, External Battery Charger	-Oxygen concentrator -AC Power Supply, -Nasal cannula -Battery -Backpack, Cart	Substantial equivalence
Alarm function	-Respiratory detection failure. -Oxygen output detection failure or low concentration. -Battery/system temperature too High or battery temperature too low. -Adapter voltage too low/high. -Battery empty or not connected or life depleted. -Airway transmission blockage -Molecular sieve replacement needed. -Compressor or fan stopped. -Gas tank pressure failure or overpressure.	-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.	-Loss of power. -Low Battery. -Low O_2 Concentration. -Gas Delivery Fail. -Absence of Breath (Only in -Pulse Mode). -System Startup Fail.	Substantial equivalence (Note 1)
Status indicator	-Tool icon -Battery status gauge -External Power Indicator -Flow Control Setting -Technical Alarm -Buzzer	-Tool icon -Battery status gauge -External Power Indicator -Flow Control Setting -Technical Alarm -Auditory buzzer	-Tool icon -Battery status gauge -External Power Indicator -Flow Control Setting -Low Priority Technical Alarm -Buzzer	Substantial equivalence

Item	HarveyMed V series (Proposed device)	Inogen Rove 6 Portable Oxygen Concentrator, K230052 (Primary predicate device)	Kingon, P2-TOC, K242718 (Secondary predicate device)	Comparisons
Power supply	AC Adaptor: a.c.100-240V 50/60Hz, 2.0-1.0A DC Adaptor: input-d.c.13.5-15.0V, output-d.c.13.5-15.0V,10A Battery type: Lithium Ion	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	AC Adaptor (Input: 100-240 VAC, 50-60 Hz) DC Adaptor (Input: 11-16 VDC Output: 19V) Battery (Lithium Ion)	Substantial equivalence (Note 2)
Filter	Air Inlet Filter	Air Inlet Filter	Air Inlet Filter	Substantial equivalence
Weight	2.2kg/4.85lbs (with standard battery) 2.6kg/5.73lbs (with long-lasting battery)	4.8 lbs (2.18kg, with standard battery) 5.8 lbs (2.63kg, with extended batter)	18.8 lbs/8.5kg (with battery)	Substantial equivalence (Note 3)
Size	18.6 * 8.4 * 20.8 cm (with standard battery version) (i.e., 8.2" * 3.3" * 7.3" inch)	8.1" * 3.3" * 7.2" (with standard 8-cell battery) (i.e., 20.6 * 8.4 * 18.3cm)	11.1 L x 6.7W x 15H (inch) 28.2 L x 17.1 W x 38.2 H (cm)	Substantial equivalence (Note 3)
Operating Environment	41°F to 104°F (5˚C to 40˚C) 0% to 90%, non-condensing 0 to 10,000 ft. (0 to 3048 meters, 70.0kPa to 101.3kPa)	41°F to 104°F (5˚C to 40°C) 15% to 90%, non-condensing 0 to 10,000 ft (0 to 3048 meters)	41°F to 104˚F (5˚C to 40˚C) 10% to 90%, non-condensing 0 to 10,000 ft. (0 to 3048 meters, 70kPa to 106kPa)	Substantial equivalence
Shipping Storage	-13°F to 158°F (-25˚C to 70˚C); 0% to 95%, non-condensing Store in a dry environment 0 to 10,000 ft (0 to 3048 meters, 70.0kPa to 101.3kPa)	-13°F to 158°F (-25˚C to 70°C); Up to 90%, non-condensing Store in a dry environment. 0 to 10,000 ft (0 to 3048 meters, 70kPa to 106 kPa)	-4°F to 158˚F (-20˚C to 70˚C) 5% to 90%, non-condensing Store in a dry environment 0 to 10,000 ft (0 to 3048 meters, 70kPa to 106 kPa)	Substantial equivalence
Oxygen delivery mode	Pulse dose and continuous mode	Pulse dose	Pulse dose and continuous mode	Substantial equivalence

<table>
<tr><th>Item</th><th>HarveyMed V series
(Proposed device)</th><th>Inogen Rove 6 Portable Oxygen Concentrator, K230052
(Primary predicate device)</th><th>Kingon, P2-TOC, K242718
(Secondary predicate device)</th><th>Comparisons</th></tr>
<tr><td>Output flow (pulse mode)</td><td>
<table>
<tr><th>BPM</th><th>Level 1</th><th>Level 2</th><th>Level 3</th><th>Level 4</th><th>Level 5</th><th>Level 6</th></tr>
<tr><td>10</td><td>21</td><td>42</td><td>63</td><td>84</td><td>100</td><td>120</td></tr>
<tr><td>15</td><td>14</td><td>28</td><td>42</td><td>56</td><td>66.7</td><td>80</td></tr>
<tr><td>20</td><td>10.5</td><td>21</td><td>31.5</td><td>42</td><td>50</td><td>60</td></tr>
<tr><td>25</td><td>8.4</td><td>16.8</td><td>25.2</td><td>33.6</td><td>40</td><td>48</td></tr>
<tr><td>30</td><td>7</td><td>14</td><td>21</td><td>28</td><td>33.3</td><td>40</td></tr>
<tr><td>35</td><td>6</td><td>12</td><td>18</td><td>24</td><td>28.6</td><td>34</td></tr>
<tr><td>40</td><td>5.25</td><td>10.5</td><td>15.8</td><td>21</td><td>25</td><td>30</td></tr>
<tr><td>Total (ml/min)</td><td>210</td><td>420</td><td>630</td><td>840</td><td>1000</td><td>1200</td></tr>
</table>
</td><td>
<table>
<tr><th>BPM</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 (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>Pulse Dose Mode: 5-133 ml Pulse Volumes, breathing rate is 15 times a minute
Pulse Dose Mode: 5-200 ml Pulse Volumes, breathing rate is 10 times a minute</td><td>Substantial equivalence (Note 4)</td></tr>
<tr><td>Output flow (continuous mode)</td><td>V5, V6: Not applicable
V5C, V6C: 1 gear, continuous Flow Mode (Mode C): 1.2 lpm</td><td>Not applicable</td><td>1-5 gear, continuous Flow Mode: 1.0-3.0 lpm</td><td>Substantial equivalence (Note 5)</td></tr>
<tr><td>Oxygen purity</td><td>≥90% at all settings</td><td>90%-3%/+6% at all settings (87%-96%)</td><td>90%-3%/+6% at all settings (87%-96%)</td><td>Substantial equivalence</td></tr>
<tr><td>Inspiratory trigger sensitivity</td><td>≤0.12 cmH2O</td><td><0.12cm/H2O</td><td>Not publicly available</td><td>Substantial equivalence</td></tr>
<tr><td>Maximum outlet pressure</td><td>< 199.3kPa (28.9 PSI)</td><td>< 28.9 PSI (199.3kPa)</td><td>Not publicly available</td><td>Substantial equivalence</td></tr>
<tr><td>Performance standard</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
ISO 80601-2-67</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
ISO 80601-2-67</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
ISO 80601-2-67</td><td>Substantial equivalence</td></tr>
<tr><td>Material of Patient contact components</td><td>Button film: PET
Main housing: PC+ABS</td><td>Not publicly available</td><td>Button panel: PET
Main housing: PC+ABS</td><td>Substantial equivalence (Note 6)</td></tr>
<tr><td>Biocompatibility</td><td>ISO 10993-1
ISO 18562-1</td><td>ISO 10993-1
ISO 18562-1</td><td>ISO 10993-1
ISO 18562-1</td><td>Substantial equivalence</td></tr>
</table>

Note 1: Although the descriptions of the alarms are different, they are all related to battery status, oxygen flow and concentration, and device status. And the subject device is tested the standard of IEC60601-1-8 and ISO80601-2-69. Therefore, the difference will not raise any different questions of safety and effectiveness for the subject device.

Note 2: Although the specifications of the AC adapter and DC connector between the subject device and predicate devices are different, the power supply of the subject device complies with the requirements of IEC60601-1, IEC60601-1-2, ISO80601-2-67, ISO80601-2-69 and IEC62133-2. Therefore, the difference will not raise any different questions of safety and effectiveness for the subject device.

Note 3: The weight and size of the subject device is similar to the Inogen Rove 6, and different from Kingon P2-TOC due to their different designs. The risk is mitigated by testing the standards of IEC60601-1, ISO80601-2-67, and ISO80601-2-69. Therefore, the difference will not raise any different questions of safety and effectiveness for the subject device.

Note 4: The pulse mode settings of the subject device are the same as the Inogen Rove 6: 6 levels/ gears, 10-40 breaths per minutes. Only the pulse volumes in gear 5 & gear 6 of the subject device is a little smaller than that of Inogen Rove 6. The risks are mitigated by testing the standards of IEC60601-1, ISO80601-2-67, ISO80601-2-69, and ISO10993-1 & ISO18562-1, as well as verification & validation by FDA's software guidance. Therefore, the difference will not raise any different questions of safety and effectiveness for the subject device.

Note 5: V5, V6 of the subject device do not have the continuous mode, which is the same as Inogen Rove 6. The flowrate range of Kingon P2-TOC is 1.0-3.0L/min with 5 gears under continuous mode, the flowrate of V5C, V6C is 1.2L/min under continuous mode, which is in the flowrate range of Kingon P2-TOC. The continuous mode is controlled by the firmware, V5C, V6C of the subject device have been designed, verified and validated the software according to FDA's software guidance to mitigate the risks of software. The risks of safety and biocompatibility are mitigated by testing the standards of IEC60601-1, ISO80601-2-67, ISO80601-2-69, and ISO10993-1 & ISO18562-1. Therefore, the difference will not raise any different questions of safety and effectiveness for the subject device.

Note 6: Materials of Inogen Rove 6 are not publicly available, but the biocompatibility evaluations including the biocompatibility tests of the subject device are carried out according to FDA biological guidance, and the results indicate that the subject device has a good biocompatibility performance. Therefore, the differences will not raise any different questions of safety and effectiveness issues for the subject device.

The subject device and the predicate devices are similar/same in indication for use, operating principle, and technology characteristics. There is no significant difference between subject device and predicate devices that raise any different questions of safety and effectiveness for the subject device.

6. Non-clinical Testing

6.1 Electrical Safety and EMC

Tests have been conducted on the subject device. The system complies with the following standards for electrical safety and EMC:

- IEC60601-1:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - requirements and tests
- IEC TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC60601-1-6:2010+A2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- IEC 60601-1-8:2020, Medical electrical device - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical device 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 device - Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving device
- ISO 80601-2-69:2020, Medical electrical device - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator device
- IEC 62133-2:2017 + A1:2021 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

6.2 Biocompatibility
The subject device is categorized as both surface contact medical device and external communication device. Evaluation and tests have been conducted in accordance with the following 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 skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 10: Tests for irritation
- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)

6.3 Performance
The following nonclinical tests were conducted with the subject device:
- Oxygen pulse volume
- Continuous flow
- Trigger sensitivity
- Oxygen concentration
- Respiratory rate
- Outlet pressure
- Low oxygen concentration alarm

6.4 Software
Software verification and validation were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff:
- Guidance for Industry and Food and Drug Administration Staff - Content of Premarket Submissions for Device Software Functions.

7. Clinical testing
Not applicable.

8. Conclusions
Based on the results of substantial equivalence assessment, and the safety and performance testing data, it concludes that the subject device is substantially equivalent to the predicate devices.