June 5, 2025

Jiangsu Yuyue Medical Equipment & Supply Co., LTD.
℅ Yijie You
Manager
Qimmiq Medical Consulting Service Co., Ltd.
RM.406, Building C, Run Science Park, No.18 Shenzhou Road,
Huangpu
Guangzhou, Guangdong 510663
China

Re: K242736
Trade/Device Name: Portable Oxygen Concentrator (Spirit-3)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: April 1, 2025
Received: April 1, 2025

Dear Yijie You:

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K242736/S001

Device Name

Portable Oxygen Concentrator (Spirit-3)

Indications for Use *(Describe)*

The Portable Oxygen Concentrator, model: Spirit-3, is intended to provide supplemental oxygen in a home, institutional, or travel environment. And the device is used with adult only, not used with pediatrics, infant, or neonate patients, etc.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) Summary

## 1. 510(k) owner (Applicant)

| | | |
|---|---|---|
| Establishment Registration number: | | 3017825461 |
| Name: | | Jiangsu Yuyue Medical Equipment & Supply Co., LTD. |
| Address: | | No.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA |
| Contact Person | Name: | Wei Yan |
| | Address: | No.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA |
| | TEL: | 86-511-86900833 |
| | Email: | weiyan@yuyue.com.cn |

## 2. Contact Person (Authorized representative)

| | |
|---|---|
| Name: | You Yijie |
| Address: | RM.406, Building C, Run Science Park, No.18 Shenzhou Road, Huangpu, Guangzhou, Guangdong 510663 P.R. China |
| TEL: | (+86)020-82245821 |
| FAX: | (+86)020-82245821 |
| Email: | jet.you@qimmiq-med.com |

Date prepared: Nov. 13, 2024

## 3. Device Information

**Device Common Name:** Generator, Oxygen, Portable
**Trade Name:** Portable Oxygen Concentrator
**Model:** Spirit-3
**Classification name:** Portable oxygen generator
**Review panel:** Anesthesiology

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| **Product code:** | CAW |
| **Regulation Class:** | II |
| **Regulation Number:** | 868.5540 |

## 4. Predicate Device and reference device Information

***Predicate device:***

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|---|---|
| 510(k) submitter/holder: | Qingdao Kingon Medical Science and Technology Co., Ltd |
| 510(K) Number: | K230702 |
| Trade Name: | Portable Oxygen Concentrator |
| Model: | P2-K4，P2-S4 |
| Classification name: | Generator, Oxygen, Portable |
| Review panel: | Anesthesiology |
| Product code: | CAW |
| Regulation Class: | II |
| Regulation Number: | 868.5440 |

***Reference device***

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|---|---|
| 510(k) submitter/holder: | Inogen, Inc. |
| 510(K) Number: | K222086 |
| Trade Name: | Inogen Rove 4 Portable Oxygen Concentrator |
| Model: | Inogen Rove 4 |
| Classification name: | Generator, Oxygen, Portable |
| Review panel: | Anesthesiology |
| Product code: | CAW |
| Regulation Class: | II |
| Regulation Number: | 868.5440 |

## 5. Device description

Portable Oxygen Concentrator, model: Spirit-3, is a portable oxygen generator that is intended to release oxygen for respiratory therapy by means of physical means (a molecular sieve). It supplies a pulsed high concentration of oxygen and is used with a nasal cannula to deliver oxygen from the concentrator to the patient. The Portable Oxygen Concentrator is small, portable and may be used in home, institutional, or travel environment.

Portable Oxygen Concentrator, model: Spirit-3, is capable of continuous use in a home, institutional, or travel environment. Power options include 100 – 240 V (50/ 60Hz) AC power supply, DC power supply and rechargeable lithium-ion battery.

The portable oxygen concentrator consists of two parts: an oxygen concentrator and accessories.

## 6. Indications for Use

The Portable Oxygen Concentrator, model: Spirit-3, is intended to provide supplemental oxygen in a home, institutional, or travel environment. And the device is used with adult only, not used with pediatrics, infant, or neonate patients, etc.

## 7. Comparison to predicate device

Comparison Analysis: The subject device is substantially equivalent to the predicate devices, Portable Oxygen Concentrator, Model: P2-K4，P2-S4 marketed by Qingdao Kingon Medical Science and Technology Co., Ltd, the substantial equivalence chart is provided as follows:

| SE<br>Comparisons | Subject device (Portable Oxygen Concentrator, model: Spirit-3 | Predicate device<br>(Kingon Portable Oxygen Concentrator, Model: P2-K4，P2-S4) | Reference device<br>(Inogen Rove™ 4 Portable Oxygen Concentrator) | Discussion of difference |
|---|---|---|---|---|
| 510K Number | / | K230702 | K222086 | / |
| Classification | 21CFR 868.5440 | 21CFR 868.5440 | 21CFR 868.5440 | Same |
| Product Code | CAW | CAW | CAW | Same |
| FDA Class | II | II | II | Same |
| Indications for Use | The Portable Oxygen Concentrator (Model: Spirit-3) is intended to provide supplemental Oxygen in a home, institutional, or Travel environment. And the device is used with adult only, not used with pediatrics, infant, or | The Portable Oxygen Concentrator (Model: P2-K4, P2-S4) is intended to provide supplemental Oxygen in a home, institutional, or Travel environment. | 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, | Same with the predicate device which is also used with adult only. |

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| | neonate patients, etc. | | institution and transport modalities. | |
| Model | Spirit-3 | P2-K4, P2-S4 | Inogen Rove 4 | / |
| Environment of Use | Home, institutional, or travel environment. | home, institutional, or travel environment. | home, institution and transport modalities | Same with the predicate device |
| Patient Population | Adult patient only | Adult | Adult patient only | Same |
| Material of Patient contact components | Top cover: PC/PMMA Coextruded film<br>Housing shell: ABS | Wiring cover: PC+ABS Intake hood: PC+ABS Nozzle fitting: Aluminum alloy<br>Button panel: PET<br>Main housing: PC+ABS | Not public | Different<br>The material of patient contact components of subject device Spirit -3 is different from predicate device P2-K4 and P2-S4 (K230702), which affect safety of biocompatibility, while not affect effectiveness. Material of subject device has been implemented biocompatibility evaluation in agreement with recommendations according to FDA Guidance-Use of International Standard ISO 10993-1, "Biological evaluation |

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| | | | | of medical devices - Part 1: Evaluation and testing within a risk management process", and Cytotoxicity, Sensitization and Irritation meet the requirement of ISO 10993- 5, ISO 10993-10 and ISO 10993-23 respectively. Therefore, the difference of subject device with predicate device do not raise new questions of safety and effectiveness. |
| Duration and type of contact | Type of contact: surface device; Duration: permanent (> 30 d); | Type of contact: surface device; Duration: permanent (> 30 d); | Externally Communicating, Tissue, Permanent Duration (>30 days) | Same with the predicate device |
| Complete list of all the biocompatibility tests performed | ISO 10993- 5 tested for Cytotoxicity;<br>ISO 10993-10 tested for Sensitization;<br>ISO 10993-23 tested for Irritation;<br>ISO 18562-2 tested for Particulate matter;<br>ISO 18562-3 tested for Volatile | ISO 10993- 5 tested for Cytotoxicity;<br>ISO 10993-10 tested for Sensitization;<br>ISO 10993-23 tested for Irritation;<br>ISO 18562-2 tested for Particulate matter;<br>ISO 18562-3 tested for Volatile organic Compounds; | ISO 18562-2 tested for Particulate matter;<br>ISO 18562-3 tested for Volatile organic Compounds; | Same with the predicate device |

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| | organic Compounds; | | | |
| Single Patient, multi-use | Yes | Yes | Yes | Same |
| Patient Interface | Cannula Port | Cannula Port | Cannula Port | Same |
| Dimensions | 22 × 8 × 22 (cm) | 17×8.6×15.7(cm) | With 4-cell battery:<br>6 x 2.7 x 7.5 in (15.1 x 6.9 x 19.1 cm)<br>With 8-cell battery:<br>6 x 2.7 x 7.8 in (15.1 x 6.9 x 19.7 cm) | Similar<br>Dimension of subject device Spirit-3(22 × 8 × 22 (cm)) is a little larger than and similar with that of predicate device P2-K4 and P2-S4 (K230702)(17×8.6×15.7(cm)), does not raise new questions of safety and effectiveness. |
| Weight | 2.4 kg (with battery) | 1.5 kg (with battery) | With 4-cell battery:<br>3.0 pounds (1.4kg)<br>With 8-cell battery:<br>3.3 pounds (1.5kg) | Similar<br>The weight of subject device Spirit-3(2.4Kg) is similar with that of predicate device P2-K4 and P2-S4 (K230702)(1.5kg), does not raise new questions of safety and effectiveness. |
| Startup time | 2 minutes | 2 minutes | 2 minutes | Same |

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| Oxygen Concentration | 90%-3%/+6% at all settings | 90%-3%/+6% at all settings | 90% - 3%/+6% at all settings | Same |
| Setting | adjustable in 1 increments from 1 to 4 | adjustable in 1 increment from 1 to 4 | adjustable in 1 increment from 1 to 4 | Same |
| Pulse mode bolus size | 37.5mL per breath at setting 4 with 20BPM | 42 mL per breath at setting 4 with 20 BPM | 42 mL per breath at setting 4 with 20 BPM | Different<br>The Pulse mode bolus size of subject device Spirit-3(37.5ml at setting 4 with 20BPM) is a little smaller than 42.0 ml at setting 4 with 20BPM of predicate device P2-K4 and P2-S4 (K230702), but is covered by the subject device, therefore the difference of subject device with predicate device do not raise new questions of safety and effectiveness. |
| Principle of operation | by means of molecular sieve | by means of molecular sieve | by means of molecular sieve | Same |
| Type of Protection Against Electrical Shock | Class II | Class II | Not public | Same with the predicate device |
| Degree of Protection | Type BF | Type BF | Not public | Same with the predicate device |

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| to Concentrator Components Against Electrical Shock: | | | | |
| Degree of Protection to Concentrator Components Against Ingress of Water | IP22 | IP22 | Not public | Same with the predicate device |
| Rated breath rate | 15 - 40 Breath per minute | 10 - 40 Breath per minute | 10 - 40 Breath per minute | Different<br>Breath rate range of the predicate device P2-K4 and P2-S4 is 10 to 40 BPM, and subject device Spirit-3 is 15 to 40 BPM, the minimum Breath rate rang for ISO80601-2-67:2020 Clause 201.12.1.101 requirement to disclosure is 15BPM, and it is also covered by the predicate device range, therefore the difference of subject device with predicate device do not raise new questions of safety and effectiveness. |

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| Work System | Work continuously | Work continuously | Work continuously | Same |
| User Interface | Buttons, LCD Display | Buttons, LCD Display | Buttons, LCD Display | Same |
| Power requirements | AC power supply: 100-240V AC, 50-60Hz,2.0A; 12.0VDC 10.0A out<br>DC Power Supply: DC 12-16V, 10A<br>Battery: DC 14.4V | AC power supply: 100-240VAC ;50-60 Hz，19VDC 5.26A out<br>DC power supply: 12 - 16V DC input，19V 6A DC output<br>Battery: not available | AC power supply:100 to 240 VAC, 50 to 60 Hz Autosensing 2.0 – 1.0A<br>DC power supply: 13.5-15.0 VDC, 100W Max voltage: 12.0 to 16.8 VDC (+ 0.5)<br>Battery：not available | Similar with the predicate device<br>The subject device Spirit-3 has same AC power supply, DC power supply and battery with those of predicate device.<br>And the subject device Spirit-3 is complied with IEC 60601-1, IEC 60601-1-2, ISO 80601-2-67 and ISO 80601-2-69. So the difference of subject device Spirit-3 with predicate device do not raise new questions of safety and effectiveness. |
| Maximum oxygen discharge pressure | 150kPa(21.8psi) | 110kPa(16.0psi) | 151.68kPa(22psi) | **Different from the predicate device, but similar with the reference device**<br>The Maximum oxygen discharge pressure of subject device Spirit-3 is 150kPa(21.8psi), is higher than 110Kpa(16.0psi) of predicate device P2-K4 and P2-S4 |

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| | | | | (K230702), but close to 22 PSI of reference device Inogen Rove 4 (K222086).<br>Therefore, the maximum oxygen discharge pressure of difference does not raise new questions of safety and effectiveness. |
| Inspiratory trigger sensitivity | -0.12 cmH2O | -0.12cmH20 | -0.12cmH20 | Same |
| Software | Embedded | Embedded | Embedded | Same |
| Acoustic Noise | 55 dBA at 0.75 LPM | 55.3dBA at 0.84LPM | Not public | Similar<br>The acoustic Noise of subject device Spirit-3 is 55 dBA at 0.75 LPM, is very close to 55.3dBA at 0.84LPM of predicate device P2-K4 and P2-S4 (K230702).<br>Therefore, the acoustic noise of subject device Spirit-3 does not raise new questions of safety and effectiveness. |

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| Alarms | Empty battery<br>Pressure failure including high pressure and low pressure<br>No flow<br>System over temperature<br>Battery over temperature<br>Compressor Failure<br>Low oxygen concentration<br>Low battery<br>No breath detected<br>Start-up failure | Battery empty<br>Low pressure<br>No pulse<br>High Temp<br>Compressor Failure<br>Fan Failure<br>Low Flow<br>Low Battery<br>No Breath Detected<br>EEPROM Failure | Not public | Different<br>The subject device Spirit-3 and predicate device P2-K4 and P2-S4 have difference in alarms, the predicate device has fan Failure and EEPROM Failure while the subject device has no such alarm for fan Failure or EEPROM Failure.<br>If the fan failure of the subject causes the system temperature to rise, and then the system over temperature alarm is active, and they have the same alarms related to the basic function of safety and performance, such as pressure, flow, system temperature, oxygen concentration, compressor, battery, breath detection, which meet the requirement of clause 201.12.4.101 and 201.12.4.102 of ISO 80601-2-67: 2020, clause 201.11.8.101.2, 201.12.4.102 and 201.13.2.101 of ISO 80601-2-69: 2020. |

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| | | | | Hence, the difference between the subject device and the predicate device does not raise new issues of safety and effectiveness. |
| Status Indicator | Flow rates | Flow rates | Flow rates | Same |
| | Battery Condition | Battery Condition | Battery Condition | Same |
| | Alarms | Alarms | Alarms | Same |
| Battery Duration | 5 hours at 0.21LPM | BA-K201: Up to 2.5 hours at 0.21 LPM;<br>BA-K200/BA-S200: Up to 4.8hours at 0.21LPM;<br>BA-K202/BA-S202: Up to 7.2 hours at 0.21LPM | Not public | Similar<br>Battery Duration at 0.21 LPM of subject device Spirit-3 is about 5 hours, which is very close to battery BA-K200/BA-S200 equipped with predicate device(4.8 hours), and battery of subject device Spirit-3 meets IEC 62133-2:2017/AMD1:2021 requirement, the battery duration does not raise any issues in safety and effectiveness. |

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| Operating Condition | Temperature: 10˚C to 35˚C<br>Humidity: 15% to 75%, non-condensing<br>Atmosphere pressure: 70kPa to 106 kPa<br>Altitude: 0 to 3000 meters | Temperature: 5 to 40˚C<br>Humidity: 10% to 90%, non-condensing<br>Atmosphere pressure: 70 to 106 kPa<br>Altitude: 0 to 3048 meters | Temperature: 41 to 104°F (5 to 40°C)<br>Humidity: 15% to 90%, non-condensing<br>Atmosphere pressure: 0 to 10,000 ft (0 to 3048 meters) | Different<br>The range of operating temperature, relative humidity, and altitude of subject device Spirit-3 is a little narrower than those of predicate deviceP2-K4 and P2-S4.<br>The performance of subject device Spirit-3 under the operating ambient is in compliance with ISO 80601-2-69 requirement, and the operating ambient is described in labeling of subject device Spirit-3. So the difference doesn't raise new questions of safety and effectiveness. |
| Storage and Transportation Condition | Temperature: -20 to +60˚C<br>Humidity: ≤93%, non-condensing<br>Atmosphere pressure: 70 to 106 kPa | Temperature: -20 to 70˚C<br>Humidity: 5% to 90%, non-condensing<br>Atmosphere pressure: 70 to 106 kPa | Temperature: -13 to 158°F (-25 to 70°C)<br>Humidity: 5% to 95%, non-condensing Store in a dry environment.<br>Atmosphere pressure: Not public | Different<br>The range of temperature ( -20 to +60˚C) of subject device Spirit-3 is a little narrower than predicate device P2-K4 and P2-S4( -20 to 70˚C);<br>The range of relative humidity (≤93%) of subject device Spirit-3 is a little wider than predicate |

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| | | | | device P2-K4 and P2-S4( 5% to 90%);<br>The range of atmospheric pressure (70 to 106 kPa) of subject device Spirit-3 is same with predicate device P2-K4 and P2-S4 (70 to 106 kPa);<br>The Storage and transport of subject device Spirit-3 under the ambient is in compliance with ASTM D4169-22, and the Storage and transport ambient is described in labeling of subject device. So the difference doesn't raise new questions of safety and effectiveness. |
| Electrical Safety | IEC 60601-1 | IEC 60601-1 | IEC 60601-1 | Same |
| Electromagnetic Compatibility | IEC 60601-1-2 | IEC 60601-1-2 | IEC 60601-1-2 | Same |
| Standards Met | ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] | ANSI AAMIES60601-1: 2005 /A1:2012 and A2:2020<br>IEC 60601-1-2: 2014<br>IEC 60601-1-11: 2015/A1:2020 | IEC 60601-1:2012<br>IEC 60601-1-2: 2020<br>IEC 60601-1-6:2020 | Different<br>While both the subject and the predicate devices have met IEC 60601-1-2 and IEC 62133-2 |

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| | IEC 60601-1-2:2014 +A1:2020<br>IEC 60601-1-11:2015 +A1:2020<br>IEC 60601-1-8:2006 +A1:2012 +A2:2020<br>IEC60601-1-6:2010 +A1:2013 + A2:2020<br>ISO 80601-2-69: 2020<br>ISO 80601-2-67: 2020<br>ISO 18562-2: 2017<br>ISO 18562-3: 2017<br>IEC 62133-2: 2017/AMD1:2021<br>ISO 10993-5:2009<br>ISO 10993-10:2021<br>ISO 10993-23:2021 | IEC 60601-1-8: 2006/ A1:2012 /A2:2020<br>IEC 60601-1-6: 2010/ A1:2013 /A2:2020<br>ISO 80601-2-69: 2020<br>ISO 80601-2-67: 2020<br>ISO 18562-2: 2017<br>ISO 18562-3: 2017<br>IEC 62133: 2017<br>ISO 10993-5:2009<br>ISO 10993-10:2021<br>ISO 10993-23:2021 | IEC 60601-1-8:2012<br>IEC 60601-1-11:2015<br>ISO 80601-2-69:2020 | requirements<br>While both the subject and the predicate devices have met IEC 60601-1-2 and IEC 62133-2 requirements, the subject device Spirit-3 satisfied the requirements of the latest version of standards, therefore the difference between subject device Spirit-3 and predicate device does not raise new questions of safety and effectiveness. |

## 8. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The device performed performance testing to demonstrate and support safety and effectiveness when compared to the predicate and the applicable standards.

| Standards | Standards Name |
|---|---|
| ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] | Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance |
| IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION | Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- 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 |
| CISPR 25: 2021 | Radio disturbance characteristics for the protection of receivers used on board vehicles, boats, and on devices - Limits and methods of measurement |
| IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION | Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests |
| IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION | 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 60601-1-6:2005/AMD2:2020 | Medical electrical equipment - Part 1-6:General requirements for basic safety and essential performance -Collateral standard: Usability |
| ISO 80601-2-69: 2020 | Medical electrical equipment. Particular requirements for the basic safety and essential performance of oxygen |

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| | concentrator equipment |
| ISO 80601-2-67: 2020 | Medical electrical equipment. Particular requirements for basic safety and essential performance of oxygen-conserving equipment |
| ISO 18562-2: 2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds |
| ISO 18562-3: 2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications. Tests for emissions of volatile organic compounds (VOCs) |
| IEC 62133-2: 2017/AMD1:2021 | Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems |
| 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 23: Tests for irritation |
| IEC 62304:2006+A1:2015 | Medical device software - Software life cycle processes |

- **Electrical Safety and Electromagnetic Compatibility Testing**

The Device was tested and complied with the applicable requirements of the following standards: ANSI AAMI ES60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-1-8, ISO 80601-2-69, ISO 80601-2-67, IEC TS 60601-4-2:2024, CISPR 25: 2021 demonstrated that the basic safety and performance of the device met the requirements.

- **Biocompatibility Testing**

According to ISO 10993-1:2018 and ISO 18562-1:2017, we performed the biocompatibility evaluation and test of skin surface direct-contacting components:

(1) In vitro Cytotoxicity test according to ISO 10993-5:2009

(2) Skin Sensitization test according to ISO 10993-10:2021 tested
(3) Irritation test according to ISO 10993-23:2021 tested

And biocompatibility evaluation and test of the breathing gas pathway:

(1) Performed test for emissions of particulate matter according to ISO 18562-2:2017.

(2) Performed test for emissions of volatile organic compounds according to ISO 18562-3:2017.

- **Software Verification and Validation**

Software verification and validation was performed, and it was demonstrated that the software performs as intended according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

The test results verified the device compliance to recognized consensus standards and therefore does not raise new questions of safety and effectiveness.

## 9. Concise summary for any performance testing

### 9.1 Summary of Performance testing – bench

The performance of device, such Sound Level, Oxygen Concentration, Flow Control Settings and Pulse Volumes, Maximum Outlet Pressure, Oxygen delivery and trigger sensitivity, was tested and complied with the applicable requirements of the following standards: ISO 80601-2-69, ISO 80601-2-67, demonstrated that the performance of the device met the requirements.

Battery safety was tested and verified via IEC 62133-2, and battery performance testing was performed which meet the requirement of performance.

### 9.2 Performance Testing – Animal

Not applicable to this submission for the Portable Oxygen Concentrator. The subject of this premarket submission, Portable Oxygen Concentrator, did not require animal studies and test results to support substantial equivalence.

### 9.3 Performance Testing – Clinical

Not applicable to this submission for the Portable Oxygen Concentrator. The subject of this premarket submission, Portable Oxygen Concentrator, did not require clinical studies to support substantial equivalence.

## 10. Substantial Equivalence Conclusion

The Portable Oxygen Concentrator, model: Spirit-3, has the same intended use and similar characteristics as the cleared predicate device Portable Oxygen Concentrator, Model: P2-K4，P2-S4.

Moreover, the portable oxygen concentrator, model Spirit-3, meets the safety and performance standards required for Portable Oxygen Concentrators, as verified by the bench tests included in this submission, which demonstrate that the differences that existed between Spirit-3 and P2-K4，P2-S4 do not raise any new questions of safety or effectiveness.

Thus, the Portable Oxygen Concentrator, model: Spirit-3 is Substantially Equivalent (SE) to the predicate device.