June 17, 2026

Honsun (Nantong) Co., Ltd.
% Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Management Consulting Co.Ltd
Room 1509, Jingting Building, Dongzhou Community,
Guangming Street, Guangming District
Shenzhen, Guangdong
China

Re: K252399
Trade/Device Name: Portable Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: June 16, 2026
Received: June 16, 2026

Dear Reanny Wang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

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)*

K252399

Device Name

Portable Oxygen Concentrator

Indications for Use *(Describe)*

The Portable Oxygen Concentrator (Model: Ares-6A, Ares-4A) provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in the home, institution, and transport modalities. This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

K252399

1. Information of Submitter and Correspondent

Submitter's information:

Company Name: HONSUN(NANTONG) CO., LTD.

Street Address: No.8,Tongxing Road,Economic&Technical Development Area

City: Nantong

State/ Province: Jiangsu

Country: China

Telephone: +86-021-63056696

Contact Person: Jian Shen (Jason)

Contact Title: RA Director

Contact Email: Jason@lordmed.com

Date Prepared: Jun. 17, 2026

Submission correspondent's information:

Shenzhen Reanny Medical Devices Management Consulting Co., Ltd

Address: Room 1509, Jingting Building, Dongzhou Community, Guangming Street, Guangming District, Shenzhen 518107, China

Contact Person: Reanny Wang

E-mail: reanny@reanny.com

Phone: +86(755) 27391220

2. Device Information

Trade Name: Portable Oxygen Concentrator (Ares-6A, Ares-4A)

Model: Ares-6A, Ares-4A

Common Name: Portable oxygen generator

Regulation Number: 21 CFR 868.5440

Regulation Name: Portable oxygen generator

Regulatory Class: Class II

Product Code: CAW(Generator, Oxygen, Portable)

3. Identification of Predicate and Reference devices

	Predicate Device	Reference device
Trade Name	Inogen Rove 6 Portable Oxygen Concentrator	Inogen Rove 4 Portable Oxygen Concentrator
510(K) Number	K230052	K222086

The predicate device and Reference device have not been subject to a design-related recall.

4. Description of Device

Portable Oxygen Concentrator (Model: Ares-6A, Ares-4A) is a portable oxygen generator that is intended to release oxygen for respiratory therapy. The Portable Oxygen Concentrator uses molecular sieve/pressure swing adsorption technology. It draws in ambient air through filters, compresses it, and passes it through a molecular sieve unit to separate oxygen from nitrogen. The oxygen is collected in a reservoir and delivered to the patient in pulse doses during inhalation. It supplies a pulsed high concentration of oxygen (90%~96%) and is used with an external nasal cannula to channel oxygen from the concentrator to the patient. The Portable Oxygen Concentrator is small, portable and may be used in home and institutional etc.

The portable oxygen concentrator consists of main unit, power adapter etc. The battery pack, molecular sieve unit, and air intake filter are replaceable parts of the main unit. The oxygen concentrator shall be used with a nasal cannula available in the market.

Model difference: The Ares-6A and Ares-4A have same intended use, fundamental principles and similar technical characteristics, apart from differences in size and appearance, the differences are as follows:

Model	Ares-6A	Ares-4A
Flow setting	Setting 1-6 (0.2L-1.2L/min)	Setting 1-4 (0.2L-0.8L/min)
Max. flow	1.2L/min	0.8L/min
power Adapter	Input: 100-240V~, 2.0~1.0A, 50-60Hz,	Input: 100~240V, 50/60Hz, 2.0A Max. output: 20.0Vdc, 4.5A

	output: 20.0Vdc. 5.0A	
Lithium Battery	utilizes 8-cell battery back, DC 14.6V, 6400mAh	utilizes 4-cell battery back, DC 14.6V, 4900mAh
Operating altitude	For setting 1 to setting 5: 0~3000m (0 ~ 9842.5ft); For setting 6: 0~1500m(0~4921ft)	0~3000m (0 ~ 9842.5ft)
Battery duration (Working hours after fully charged)	1.3~3h(error: ±30%)	65~160min(error: ±30%)
Battery charging time	≤ 2.5 hours	≤ 2 hours

5. Indications for Use

The Portable Oxygen Concentrator (Model: Ares-6A, Ares-4A) 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.

6. Comparison of Intended Use and Technological Characteristics of the Subject Device and Predicate Devices.

The Portable Oxygen Concentrator submitted in this 510(k) submission is substantially equivalent in intended use, technological characteristics and performance to the cleared Portable Oxygen Concentrator **K230052**. Differences between the subject and predicate device do not raise new questions of safety and effectiveness.

Device	**Subject device(K252399)** Portable Oxygen Concentrator (Ares-6A, Ares-4A)	**Primary Predicate device**(K230052) Inogen Rove 6 Portable Oxygen Concentrator	**Reference device**(K222086) Inogen Rove 4 Portable Oxygen Concentrator	**Comparison**
Classification	Generator, Oxygen, Portable	Generator, Oxygen, Portable	Generator, Oxygen, Portable	Same
Regulation	Class II, 21 CFR 868.5440)	Class II, 21 CFR 868.5440	Class II, 21 CFR 868.5440	Same
Product code	CAW	CAW	CAW	Same
Indication for Use/intended use	The 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 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 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.	Same
Prescriptive	Yes	Yes	Yes	Same
Fundamental scientific technology	Breath detection technology Molecular Sieve/pressure swing adsorption technology	Breath detection technology Molecular Sieve/pressure swing adsorption technology	• Breath detection technology • Molecular Sieve/pressure swing adsorption technology	Same
Patient use	Adult Patients requiring respiratory therapy on a prescriptive basis.	Adult Patients requiring respiratory therapy on a prescriptive basis.	Adult patient only	Same
User/Patient Interface	User interface panel	User interface panel	User interface panel	Same
	LCD Display to convey information about operating status in numbers and symbols.	LCD Display to convey information about operating status in numbers and symbols.	LCD Display to convey information about operating status in numbers and symbols.	Same
	Alarm indicator light - yellow or red alarm indication that illuminates to indicate abnormal operating conditions in compliance with IEC 60601-1-8	Alarm Indicator - yellow LED on UIP above “Alarm/Warning” triangle symbol that illuminates to indicate abnormal operating conditions in compliance with IEC 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	Similar

	Breath Detect Notification -when a breath is detected, and an oxygen pulse is triggered, emit the Breath Detect Notification.	Breath Detect Notification - when a breath is detected, and an oxygen pulse is triggered, emit the Breath Detect Notification.	Breath Detect Notification – Green LED on UIP illuminates when a breath is detected, and an oxygen pulse is triggered.	Same
	Auditory Buzzer - Audible beeps are emitted to indicate alarm or status change conditions in compliance with IEC 60601-1-8.	Auditory Buzzer - Audible beeps are emitted to indicate alarm or status change conditions in compliance with IEC 60601-1-8.	Auditory Buzzer – Audible beeps are emitted to indicate alarm or status change conditions in compliance with ISO 60601-1-8.	Same
	Battery release - Patient removable battery using battery buckle to release battery then slide off bottom of concentrator.	Battery release latch- Patient removable battery using push latch to release battery then slide off bottom of concentrator.	Not publicly available	Same
	Molecular sieve unit - Users must send device to provider for Molecular sieve unit replacement. users shall not replace the molecular sieve unit by themselves.	Sieve beds - Users may send device to provider for sieve bed replacement, or users may replace sieves. Sieve beds are user replaceable by pulling the wire handle while depressing the retaining tab to pull the columns out. The replacement columns are installed by pushing them in until the retaining tab snaps into place.	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.	Similar
	Accessories available to the user include: Battery pack, Power adaptor, Pull Ring, Carry bag	Optional accessories - Carry Bag, Backpack, Cart, External Battery Charger	Optional accessories - Carry Bag, Backpack, External Battery Charger	Similar
	Use the power adapter to charge the battery of concentrator.	External Battery Charger (EBC) - Optional accessory. Independent battery charger that utilizes an AC/DC power supply. The EBC slides onto the Inogen Rove 6 battery to charge outside of the concentrator.	External Battery Charger - Optional accessory. – Utilizes AC power supply and cord for power and charging	Similar
	There is no mobile application available. Viewing device settings, battery information, and current alerts on the concentrator display only.	Inogen Connect Mobile Application - Optional mobile application for viewing device settings, battery information, and current alerts, available for iOS and Android in English, French.	Inogen Connect Mobile Application – Optional mobile application for viewing device settings, battery information, and current alerts, available for iOS and Android in English, French	Different
	User Manual – Device information including Indications for Use, Contraindications and Precautions, Operating Principles, Cautions and	User Manual – Device information including Indications for Use, Contraindications and Precautions, Operating Principles, Cautions and	User Manual – Device information including Indications for Use, Contraindications and Precautions, Operating Principles, Cautions and	Same

	Warnings, Device Descriptions, General Instructions, Audible and Visible Signals, Alarm/Alert System, Troubleshooting, Cleaning, Care and Maintenance, and Specifications and Technical Description	Warnings, Device Descriptions, General Instructions, Audible and Visible Signals, Alarm/Alert System, Troubleshooting, Cleaning, Care and Maintenance, and Specifications and Technical Description	Warnings, Device Descriptions, General Instructions, Audible and Visible Signals, Alarm/Alert System, Troubleshooting, Cleaning, Care and Maintenance, and Specifications and Technical Description	
Operating System	Software monitored	Software monitored	Software monitored	Same
Bluetooth Technology	No Mobile Application	Inogen Connect App - BLE Connection to Android or iPhone. The Inogen Rove 6 Oxygen Concentrator is capable of Bluetooth functionality with the Inogen Connect App.	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.	Different
Components	Power Adapter(100-240V~ 50-60Hz) is used for power supply and charging.	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.	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.	Similar
	Cannula -- Patient breaths through off the shelf nasal cannula attached to a metal oxygen outlet on the concentrator.	Cannula --Patient breaths through off the shelf nasal cannula attached to a metal cannula barb on the concentrator.	Cannula – Is user supplied off-the-shelf	Same
	Battery – utilizes a 4-cell (Ares-4A) or 8-cell(Ares-6A) lithium battery. To attach the battery, slide it on to the base of the concentrator. Battery release – user removable battery by pulling down the battery buckle and slide the battery off the device.	Battery – utilizes an 8 or 16-cell lithium battery. To attach the battery, slide it on to the base of the concentrator. Battery release latch – Patient removable battery by pressing and holding the battery latch button and slide the battery off the device.	Battery – utilizes a 4 or 8-cell lithium battery. To attach the battery, slide it on to the base of the concentrator.	Similar
Size	Ares-6A: L195×W96×H208 (mm) , tolerance:±10mm;	With standard 8-cell battery: 8.1” H, 3.3” W, 7.2” D	With 4-cell battery: 7.5”H, 6.0” W, 2.7” D	Different

	Ares-4A: L173×W83×H193 (mm) , tolerance:±10mm;			
Weight	Ares-6A: 2.2kg±15% (including battery) Ares-4A: 1.7kg±15% (including battery)	With Standard Battery: 4.8 lbs With Extended Batter: 5.8 lbs	With 4-cell battery: 3.0 pounds (1.4kg) With 8-cell battery: 3.3 pounds (1.5kg)	
Principle of Operation	The Portable Oxygen Concentrator uses molecular sieve/pressure swing adsorption technology. Ambient air is drawn through air intake filters by a compressor and forced through molecular sieve unit, 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 units, manifolds and precision valves, sensors and embedded software are used to control the cycle to make the system function. Oxygen is delivered to the patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. the Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, through a final filter, into the connected nasal cannula and on to the patient	The Inogen Rove 6 Portable Oxygen Concentrator uses molecular sieve/pressure swing adsorption technology. Ambient air is drawn through particle filters by a compressor and forced through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. The airflow is then changed, and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Oxygen is collected in an accumulator reservoir. Waste nitrogen is exhausted back into the room. A series of sieve beds, manifolds and precision valves, sensors and embedded software are used to control the cycle to make the system function. Oxygen is delivered to the patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. Inogen Rove 6 Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, through a final filter, into the connected nasal cannula and on to the patient.	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,	Same

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<td>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</td>
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<tr>
<td>Oxygen Delivery Mode</td>
<td>Pulse Dose</td>
<td>Pulse Dose</td>
<td>Pulse Dose</td>
<td>Same</td>
</tr>
<tr>
<td>Output Flow</td>
<td>Pulse Volumes per flow setting
(Pulse volumes (ml) +/- 15%, per ISO 80601-2-67)
For Ares-6A:
<table>
<tr><th>BREATHS PER MINUTE</th><th>Setting 1</th><th>Setting 2</th><th>Setting 3</th><th>Setting 4</th><th>Setting 5</th><th>Setting 6</th></tr>
<tr><td>10</td><td>20.0</td><td>40.0</td><td>60.0</td><td>80.0</td><td>100.0</td><td>120.0</td></tr>
<tr><td>15</td><td>13.33</td><td>26.67</td><td>40.0</td><td>53.33</td><td>66.67</td><td>80.0</td></tr>
<tr><td>20</td><td>10.0</td><td>20.0</td><td>30.0</td><td>40.0</td><td>50.0</td><td>60.0</td></tr>
<tr><td>25</td><td>8.0</td><td>16.0</td><td>24.0</td><td>32.0</td><td>40.0</td><td>48.0</td></tr>
<tr><td>30</td><td>6.67</td><td>13.33</td><td>20.0</td><td>26.67</td><td>33.33</td><td>40.0</td></tr>
<tr><td>35</td><td>5.71</td><td>11.43</td><td>17.14</td><td>22.85</td><td>28.57</td><td>34.39</td></tr>
<tr><td>40</td><td>5.0</td><td>10.0</td><td>15.0</td><td>20.0</td><td>25.0</td><td>30.0</td></tr>
<tr><td>TOTAL VOLUME PER MINUTE (L/min)</td><td>0.2</td><td>0.4</td><td>0.6</td><td>0.8</td><td>1.0</td><td>1.2</td></tr>
</table>
For Ares-4A:
<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>20.0</td><td>40.0</td><td>60.0</td><td>80.0</td></tr>
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<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>
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<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>
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</table>
</td>
<td>Similar</td>
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	20	10.0	20.0	30.0	40.0		
	25	8.0	16.0	24.0	32.0		
	30	6.67	13.33	20.0	26.67		
	35	5.71	11.43	17.14	22.85		
	40	5.0	10.0	15.0	20.0		
	TOTAL VOLUME PER MINUTE (L/min)	0.2	0.4	0.6	0.8		
Oxygen Purity	90~96% (93%±3%) at all settings					90% - 3%/+6% at all settings	90% - 3%/+6% at all settings	Similar
Maximum Outlet Pressure	≤200kPa					< 28.9 PSI (199 kPa)	< 22 PSI 18.7 PSI (129 kPa) ± 10%	Similar
Inspiratory trigger pressure sensitivity	<0.12 cm H_20					<0.12 cm H_20	<0.12 cm H_20	Same
Performance Electrical Safety and EMC	AAMI/ANSI ES 60601-1ES60601-1:2005/(R)2012 AMD2:2021 IEC 60601-1-2: 2020 IEC 60601-1-8:2020 IEC 60601-1-11:2020 ISO 80601-2-69:2020 ISO 80601-2-67:2020					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 • 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 • ISO 80601-2-67:2020 • IEC 62366-1	Same
Power / Energy Source	Power Adapter(100-240V~ 50-60Hz) is used for power supply and charging. Battery – utilizes a 4-cell (Ares-4A) or 8-cell(Ares-6A) lithium battery.					AC/DC Power Adapter – Utilizes 100-240V, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator. DC Power Cable - cord and adapter to allow for connection to 12-volt DC outlet with cigarette lighter connector and barrel jack connection to concentrator. Battery - utilizes an 8 or 16-cell rechargeable lithium battery	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.	Similar
Biocompatibility	Externally Communicating, Tissue, Permanent Duration (>30 days) ISO 18562-2: 2024 Particulate matter ISO 18562-3:2024 Volatile organic					Externally Communicating, Tissue, Permanent Duration (>30 days) ISO 18562-2 Particulate matter ISO 18562-3 Volatile organic compounds	Externally Communicating, Tissue, Permanent Duration (>30 days) ISO 18562-2: 2017 Particulate matter	Same

	compounds		ISO 18562-3:2017 Volatile organic compounds	
Maximum Daily Use Time	5 hours	8 hours	5 hours	The same as the reference device

The subject and predicate device have same indications for use statements and the same intended use, i.e. provide a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis, and the device is not intended to be life sustaining or life supporting.

As noted in the table above, the technological differences between the subject and the predicate device include differences in User/Patient Interface, Bluetooth Technology, Components,Output Flow, Oxygen Purity, Maximum Outlet Pressure, Power / Energy Source, Maximum Daily Use Time, Size and Weight. These technological differences do not raise different questions of safety and effectiveness and can be evaluated through performance testing.

7. Discussion of Non-Clinical Testing:

Performance Testing Summary

The following performance data were provided in support of the substantial equivalence determination:

1) Biocompatibility Testing

- 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 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: Tests for emissions of volatile organic compounds

2) Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Wearable Breast Pump device. The system complies with the following standards:

- IEC 60601-1 Edition 3.2 2020-08 Medical electrical equipment – Part1: General requirements for basic safety, and essential performance
- IEC 60601-1-11 Edition 2.1 2020-07 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
- IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances-Requirements and tests standard for EMC
- IEC 62133-2 Edition 1.1 2021-07 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
- ISO 80601-2-69 Second edition 2020-11 Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment
- IEC 60601-1-8 Edition 2.2 2020-07 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

3) Software Verification and Validation Testing

Software verification and validation was conducted as recommended in the 2023 FDA guidance document, “Content of Premarket Submissions for Device Software Functions” consistent with a basic documentation level.

8. Conclusions

The results of the performance testing described above demonstrate that the subject device (Ares-4A, Ares-6A) is as safe and effective as the predicate device and supports a determination of substantial Equivalence.