

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

			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																																																			
Oxygen Delivery Mode	Pulse Dose		Pulse Dose					Pulse Dose	Same																																													
Output Flow	Pulse Volumes per flow setting (Pulse volumes (ml) +/- 15%, per ISO 80601-2-67) For Ares-6A:							<table><tr><td>BREATHS PER MINUTE</td><td>Setting 1</td><td>Setting 2</td><td>Setting 3</td><td>Setting 4</td></tr><tr><td>10</td><td>21.0</td><td>42.0</td><td>63.0</td><td>84.0</td></tr><tr><td>15</td><td>14.0</td><td>28.0</td><td>42.0</td><td>56.0</td></tr><tr><td>20</td><td>10.5</td><td>21.0</td><td>31.5</td><td>42.0</td></tr><tr><td>25</td><td>8.4</td><td>16.8</td><td>25.2</td><td>33.6</td></tr><tr><td>30</td><td>7.0</td><td>14.0</td><td>21.0</td><td>28.0</td></tr><tr><td>35</td><td>6.0</td><td>12.0</td><td>18.0</td><td>24.0</td></tr><tr><td>40</td><td>5.25</td><td>10.5</td><td>15.75</td><td>21.0</td></tr><tr><td>TOTAL VOLUME PER MINUTE (ml/min)</td><td>210</td><td>420</td><td>630</td><td>840</td></tr></table>	BREATHS PER MINUTE	Setting 1	Setting 2	Setting 3	Setting 4	10	21.0	42.0	63.0	84.0	15	14.0	28.0	42.0	56.0	20	10.5	21.0	31.5	42.0	25	8.4	16.8	25.2	33.6	30	7.0	14.0	21.0	28.0	35	6.0	12.0	18.0	24.0	40	5.25	10.5	15.75	21.0	TOTAL VOLUME PER MINUTE (ml/min)	210	420	630	840	Similar
BREATHS PER MINUTE	Setting 1	Setting 2	Setting 3	Setting 4																																																		
10	21.0	42.0	63.0	84.0																																																		
15	14.0	28.0	42.0	56.0																																																		
20	10.5	21.0	31.5	42.0																																																		
25	8.4	16.8	25.2	33.6																																																		
30	7.0	14.0	21.0	28.0																																																		
35	6.0	12.0	18.0	24.0																																																		
40	5.25	10.5	15.75	21.0																																																		
TOTAL VOLUME PER MINUTE (ml/min)	210	420	630	840																																																		
	BREATHS PER MINUTE																																																					
	10																																																					
	15																																																					
	20																																																					
	25																																																					
	30																																																					
	35																																																					
	40																																																					
	TOTAL VOLUME PER MINUTE (L/min)																																																					
	For Ares-4A:																																																					
	BREATHS PER MINUTE																																																					
	10																																																					
	15																																																					

	20 25 30 35 40 TOTAL VOLUME PER MINUTE (L/min)	10.0	20.0	30.0	40.0			
		8.0	16.0	24.0	32.0			
		6.67	13.33	20.0	26.67			
		5.71	11.43	17.14	22.85			
		5.0	10.0	15.0	20.0			
		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 ₂ O					<0.12 cm H ₂ O	<0.12 cm H ₂ O	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.