



September 23, 2026

Oxytek Medical Technology Co., Ltd.
% Cassie Lee
Share Info (Guangzhou) Medical Consultant , Ltd.
1919-1920, Bldg. D3, Minjie Plaza, Shuixi Rd.,
Huangpu District
Guangzhou, Guangdong 51000
China

Re: K254289

Trade/Device Name: Portable Oxygen Concentrator (OX-1A-E, OX-1B)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: August 23, 2026
Received: August 24, 2026

Dear Cassie Lee:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,


JAMES J. LEE -S

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

Enclosure

Indications for Use

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

K254289

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Please provide the device trade name(s).

?

Portable Oxygen Concentrator (model: OX-1A-E, OX-1B)

Please provide your Indications for Use below.

?

The Portable Oxygen Concentrator only delivers pulsatile oxygen, provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institution, boat, vehicle, aircraft, and other transport modalities. These devices are to be used as an oxygen supplement and are not intended to be life sustaining or life supporting.

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Sponsor Name: Oxytek Medical Technology Co.,Ltd.
Address: Room 801, 802, Building 8, CIMC High tech Intelligent Manufacturing Center, No. 3 Chanxing 1st Road, Xianchong Village, Chencun Town, Shunde District, Foshan City, Guangdong, China
Contact Person (including title): Jenny Liu (Manager)
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Application Correspondent:

Application Correspondent:
Contact Person: Ms. Cassie Lee
Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel: +86 20 8266 2446
Email: 382198657@qq.com

2. Subject Device Information

Trade Name: Portable Oxygen Concentrator
Model: OX-1A-E, OX-1B
Regulation: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW

3. Predicate Device Information

Sponsor: Inogen, Inc
Trade Name: Inogen Rove 6 Portable Oxygen Concentrator
Regulation: 21 CFR 868.5440
510(k) Number: K230052
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II

Product Code: CAW

4. Device Description

The Portable Oxygen Concentrator (model: OX-1A-E, OX-1B) is a portable oxygen generator that provides supplemental oxygen to patients requiring respiratory therapy. It may be used in home, institutional, or travel environment. It is used with a nasal cannula to channel oxygen from the device to the patient.

The Portable Oxygen Concentrator (model: OX-1A-E, OX-1B) 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. Oxygen is collected in an accumulator reservoir. Waste nitrogen is exhausted back into the room. Oxygen is delivered to the patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle. This conserves technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. All the setting of the two models are the same, the difference between the two models is the appearance and the capacity of battery

5. Intended Use / Indications for Use

The Portable Oxygen Concentrator only delivers pulsatile oxygen, provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institution, boat vehicle, aircraft, and other transport modalities.

These devices are to be used as an oxygen supplement and are not intended to be life sustaining or life supporting.

6. Test Summary

6.1 Summary of Non-Clinical Performance Testing

Performance Testing Summary

The Portable Oxygen Concentrator (Model: OX-1A-E, OX-1B) has been thoroughly evaluated for electrical safety and performance and has been found to conform to the following standards.

1) Electrical safety and electromagnetic compatibility (EMC)

- IEC 60601-1: 2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances
- 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
- 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.

- IEC 60601-1-8: 2020 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- ISO 80601-2-69: 2020 Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment
- ISO 80601-2-67: 2020 Particular requirements for basic safety and essential performance of oxygen-conserving equipment

2) 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: 2017 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

3) Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

6.2 Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

7. Comparison to predicate device and conclusion

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Primary Predicate Device	Verdict
Company	Oxytek Medical Technology Co.,Ltd.	Inogen, Inc.	--
Trade Name	Portable Oxygen Concentrator	Inogen Rove 6 Portable Oxygen Concentrator	--
Model	OX-1A-E, OX-1B	Inogen Rove 6)	--
510(k) Number	Applying	K230052	--
Product Code	CAW	CAW	Same
Device classification	Class II	Class II	Same
Regulation number	21 CFR 868.5440	21 CFR 868.5440	Same
Intended Use and Indications.	The Portable Oxygen Concentrator only delivers pulsatile oxygen, provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institution, boat, vehicle, aircraft, and other transport modalities. These devices are to be used as an oxygen supplement and are not intended to be life sustaining or life supporting.	The Inogen Rove 6 Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institution, and transport modalities. This device is to used as an oxygen supplement and is not intended to be life sustaining or life supporting.	Same Note 1
Prescriptive	Yes	Yes	Same
Fundamental scientific technology	- Breath detection technology - Molecular sieve/pressure swing adsorption technology	- Breath detection technology - Molecular sieve/pressure swing adsorption technology	Same
Patient use	Patients requiring supplemental oxygen	Patients requiring supplemental oxygen	Same
User/Patient Interface	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.	Same

Elements of Comparison	Subject Device	Primary Predicate Device	Verdict
	Alarm Indicator - yellow LED on main unit above Alarm 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	Same
	Breath Detect Notification – Green LED on UIP illuminates when a breath is detected, and an oxygen pulse is triggered.	Breath Detect Notification – Green LED on UIP illuminates when a breath is detected, and an oxygen pulse is triggered.	Same
	Auditory Speaker – Audible beeps are emitted to indicate alarm or status change 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.	Same
	Battery release latch ● Model OX-1A-E: the battery is non-detachable ● Model OX-1B: patient removable battery by pushing the slider on the battery (indicated by the arrow) and pull the battery out in the direction of the slider.	Battery release latch - Patient removable battery using push latch to release battery then slide off bottom of concentrator.	Similar Note 2
	Sieve beds - Do not disassemble or replace the metal columns without authorization. Only authorized after-sales engineers from the equipment supplier or manufacturer can disassemble or replace the metal columns.	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.	Similar Note 3
	Filter - Patient instructed to replace the filter every 6 months or every 1500 hours.	Particle Filter - Patient instructed to clean particle filters once per week.	Similar Note 4
	Optional accessories -no optional accessories	Optional accessories - Carry Bag, Backpack, Cart, External Battery Charger	Similar Note 5
	One AC supply adapter and DC power cable are standard configuration.	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.	Similar Note 5

Elements of Comparison	Subject Device	Primary Predicate Device	Verdict
	No mobile application for the subject device	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 Note 6
	User Manual – Device information including principle of operations and intended use, safety information, instructions and training, product description, operating instruction, alarm indicators and screen symbol, troubleshooting, maintenance and cleaning, device repair and disposal, technical descriptions, symbols, EMC information.	User Manual – Device information including Indications for Use, Contraindications and Precautions, Operating Principles, Cautions and Warnings, Device Descriptions, General Instructions, Audible and Visible Signals, Alarm/Alert System, Troubleshooting, Cleaning, Care and Maintenance, and Specifications and Technical Description.	Similar Note 7
Operating system	Software monitored	Software monitored	Same
Bluetooth technology	NA. No Bluetooth technology for the subject device.	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	Different Note 8
Components	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.	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.	Same
	DC Power Cable – cord and power plug to allow for connection to 12VDC-20VDC outlet with cigarette lighter connector 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 Note 9
	Cannula -- Patient breaths through off the shelf nasal cannula attached to a recessed metal cannula barb on the concentrator.	Cannula -- Patient breaths through off the shelf nasal cannula attached to a recessed metal cannula barb on the concentrator.	Same
	Battery – utilizes an 8 lithium battery. The battery of OX-1A-X is not removable.	Battery – utilizes an 8 or 16-cell lithium battery. To attach the battery, slide it on to the base of the concentrator.	Similar Note 10

Elements of Comparison	Subject Device	Primary Predicate Device	Verdict
	The battery of OX-1B is removable: To attach the battery, insert the new battery into the corresponding slot of the oxygen concentrator and ensure that the battery is not loose. Battery release latch – Push the slider on the battery and pull the battery out in the direction of the slider.	Battery release latch – Patient removable battery by pressing and holding the battery latch button and slide the battery off the device.	
Size	OX-1A-X: 115(L) x 158(W) x 255(H) OX-1B: 180(L) x 80(W) x 210(H)	With standard 8-cell battery: 8.1" H, 3.3" W, 7.2" D	Similar Note 11
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 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 oxygen tank. Waste nitrogen is exhausted back into the room. Sieve beds, control valve, sensor 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. Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the oxygen tank 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.	Same
Performance			
Oxygen delivery mode	Pulse dose	Pulse dose	Same

Elements of Comparison	Subject Device							Primary Predicate Device							Verdict																																																															
Output flow	OX-1A-E							<table><tr><td>Breat hs per minut e</td><td>Settin g 1</td><td>Settin g 2</td><td>Settin g 3</td><td>Settin g 4</td><td>Settin g 5</td><td>Settin g 6</td></tr><tr><td>10</td><td>21.0</td><td>42.0</td><td>63.0</td><td>84.0</td><td>105.0</td><td>126.0</td></tr><tr><td>15</td><td>14.0</td><td>28.0</td><td>42.0</td><td>56.0</td><td>70.0</td><td>84.0</td></tr><tr><td>20</td><td>10.5</td><td>21.0</td><td>31.5</td><td>42.0</td><td>52.5</td><td>63.0</td></tr><tr><td>25</td><td>8.4</td><td>16.8</td><td>25.2</td><td>33.6</td><td>42.0</td><td>50.4</td></tr><tr><td>30</td><td>7.0</td><td>14.0</td><td>21.0</td><td>28.0</td><td>35.0</td><td>42.0</td></tr><tr><td>35</td><td>6.0</td><td>12.0</td><td>18.0</td><td>24.0</td><td>30.0</td><td>36.0</td></tr><tr><td>40</td><td>5.25</td><td>10.5</td><td>15.75</td><td>21.0</td><td>26.3</td><td>31.5</td></tr><tr><td>Total volum e per minut e (ml/mi n)</td><td>210</td><td>420</td><td>630</td><td>840</td><td>1050</td><td>1260</td></tr></table>							Breat hs per minut e	Settin g 1	Settin g 2	Settin g 3	Settin g 4	Settin g 5	Settin g 6	10	21.0	42.0	63.0	84.0	105.0	126.0	15	14.0	28.0	42.0	56.0	70.0	84.0	20	10.5	21.0	31.5	42.0	52.5	63.0	25	8.4	16.8	25.2	33.6	42.0	50.4	30	7.0	14.0	21.0	28.0	35.0	42.0	35	6.0	12.0	18.0	24.0	30.0	36.0	40	5.25	10.5	15.75	21.0	26.3	31.5	Total volum e per minut e (ml/mi n)	210	420	630	840	1050	1260	Similar Note 12
	Breat hs per minut e	Settin g 1	Settin g 2	Settin g 3	Settin g 4	Settin g 5	Settin g 6																																																																							
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	40	5.38	10.00	15.00	20.00	25.00	30.00																																																																							
	OX-1B:																																																																													
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Breath per minute	1 200mL	2 400mL	3 600mL	4 800mL	5 1000m L	6 1200m L																																																																								
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35	5.71	11.43	17.10	22.90	28.60	34.30																																																																								
40	5.00	10.00	15.00	20.00	25.00	30.00																																																																								
Oxygen purity	93±3% at all settings							90% -3%/+6% at all settings							Similar Note 13																																																															
Maximum output pressure	15 psi							< 28.9 PSI (199 kPa)							Similar Note 14																																																															

Elements of Comparison	Subject Device	Primary Predicate Device	Verdict
Performance standards			
Performance electrical safety and EMC	IEC 60601-1: 2020 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 62366-1	IEC 60601-1:2012 IEC 60601-1-2: 2012 IEC 60601-1-8: 2012 IEC 60601-1-11: 2015 ISO 80601-2-69: 2020 ISO 80601-2-67: 2020 IEC 62366-1	Similar Note 15
Biocompatibility	Externally Communicating, Tissue, Permanent Duration (>30 days) ISO 18562-2:2017 Particulate matter ISO 18562-3: 2024 Volatile organic compounds	Externally Communicating, Tissue, Permanent Duration (>30 days) ISO 18562-2: 2017 Particulate matter ISO 18562-3:2017 Volatile organic compounds	Similar Note 16

Comparison in Detail(s):

Note 1:

Based on the working principle of the subject device and predicate device, both of them delivery pulsatile oxygen and provide high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. And the subject device meets the requirement of IEC 60601-1-12. Therefore, the slightly difference of the indication for use will not raise safety or effectiveness issues.

Note 2:

The battery release method is different in description, and the subject device meets the requirement of IEC 62366-1. This difference will not raise safety or effectiveness issues.

Note 3:

The Sieve beds of subject device should be replaced by authorized after-sale engineers, users could not replace by themselves. This difference will not raise safety or effectiveness issues.

Note 4:

Though the clean frequency and replacement requirement are different from the predicate device, the maintenance requirement of filter is clear in user manual. So the difference will not raise safety or effectiveness issue.

Note 5:

Though the accessories of subject device is a little different from predicate, the difference will not raise any safety or effectiveness issue.

Note 6:

The mobile application of the predicate device is just for viewing device settings, battery information, and current alerts. These information can be read in the display panel of the subject device. Therefore, this difference will not raise safety or effectiveness issues.

Note 7:

Though the chapter name of the user manual is different from those of predicate device, the content is similar. So, the difference will not raise safety or effectiveness issues.

Note 8:

The function of Bluetooth technology of predicate device is for connecting the main unit with the mobile application, to view the device settings, battery information, and current alerts. These information can be read in the display panel of the subject device. Therefore, this difference will not raise safety or effectiveness issues.

Note 9:

The voltage of the DC power is a little from the predicate device, but the subject device meets the requirement of IEC 60601-1, IEC 60601-1-11, ISO 80601-2-69 and ISO 80601-2-67. So, this difference will not raise safety or effectiveness issues.

Note 10:

Though the method to attach or release the battery of OX-1B is a little difference in description. But it will not raise safety or effectiveness issues.

Note 11:

The size of subject device is a little different from the predicate device, but it will not raise safety or effectiveness issues.

Note 12:

The output flow of subject device is very close to the predicate device. And the device meets the requirement of ISO 80601-2-69 and ISO 80601-2-67. So, this slightly difference will not raise safety or effectiveness issue.

Note 13:

The oxygen purity of subject device is within the range of predicate device, and the subject device meets the requirement of ISO 80601-2-69 and ISO 80601-2-67. So, the slightly difference will not raise safety or effectiveness issues.

Note 14:

The maximum output pressure is smaller than the predicate device, and the subject device meets the requirement of ISO 80601-2-69 and ISO 80601-2-67. So, the slightly difference will not raise safety or effectiveness issues.

Note 15:

Both the subject device and predicate device meet the requirement of same standards, and the subject device meets the requirement of the latest standards. So, the difference of version will not raise the safety or effectiveness issues.

Note 16:

Both the subject device and predicate device meet the requirement of same standards, and the subject device meets the requirement of the latest standards. So, the difference of version will not raise the safety or effectiveness issues.

Final Conclusion:

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device K230052.

8. Date of the summary prepared: September 23, 2026