May 29, 2026

Oxytek Medical Technology Co., Ltd.
% Cassie Lee
Primary Correspondent
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road
Huangpu District
Guangzhou, Guangdong 51000
China

Re: K252965
Trade/Device Name: Oxygen Concentrator (OX-5A, OX-5C)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: April 17, 2026
Received: April 17, 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.

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

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.	K252965

Please provide the device trade name(s).

Oxygen Concentrator (OX-5A, OX-5C)

Please provide your Indications for Use below.

The oxygen concentrator provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve, it can be used in the home or health care facility. It is not intended to sustain or support life. The intended patient should be 22 years old and above.

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

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

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 878.4810.

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
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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: Oxygen Concentrator
Model: OX-5A, OX-5C
Regulation: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW

3. Predicate Device Information

Sponsor: Jiangsu Jumao X-Care Medical Equipment Co., Ltd.
Trade Name: Oxygen concentrator
Regulation: 21 CFR 868.5440
510(k) Number: K230969
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW

4. Device Description

The Oxygen Concentrator is made up of mainframe and flowmeter. It is an electronically operated device that separates oxygen from ambient air. It provides high concentration of oxygen directly to patient/user through a nasal cannula.

The oxygen concentrator is a Pressure Swing Adsorption (PSA) type oxygen concentrator. The output of oxygen is 0.5 to 5 liter per minute, tolerance is ±10% or ±200ml/min, whichever is greater. Room air enters the compressor via filter for removing dust particles. The output compressed air is directly by a pneumatic valve into sieve bed which is full of adsorption material-molecular sieve. Nitrogen is absorbed by the molecular sieve as the pressure increases; oxygen flows through the molecular sieve and concentrates at the sieve bed bottom. The pressurized oxygen is regulated down to the suitable pressure, and adjustable flow meter and out to the patient.

Two sieve beds exchange the role of oxygen concentration and continue to produce 93%±3% oxygen to the patient.

The maximum altitude the subject device can operate without degradation of concentration is 2000m.

5. Intended Use / Indications for Use

The oxygen concentrator is intended to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life. The intended patient should above 22 years old.

6. Test Summary

6.1 Summary of Non-Clinical Performance Testing

Performance Testing Summary

The Oxygen Concentrator (Model: OX-5A, OX-5C) 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 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

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: 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

3) Usability Testing

Usability testing was conducted on the Oxygen Concentrator (Model: OX-5A, OX-5C), the device complies with IEC 62366-1 and IEC 60601-1-6.

4) 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.

Table 1: Comparison between model OX-5A and K230969

Elements of Comparison	Subject Device	Primary Predicate Device	Verdict
Company	Oxytek Medical Technology Co.,Ltd.	Jiangsu Jumao X-Care Medical Equipment Co., Ltd.	--
Trade Name	Oxygen Concentrator	Portable oxygen generator	--
Model	OX-5A	JMC5A Ni	--
510(k) Number	K252965	K230969	--
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 oxygen concentrator is intended to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life. The intended patient should above 22 years old.	The JUMAO Oxygen Concentrator is intended to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.	Same Note 1
Intended patient population	The device is intended for use in adults.	The device is intended for use in adults.	Same
Structure and main components	The Oxygen Concentrator is made up of mainframe and flowmeter. The front panel of the device contains the controls and indicators. These include an oxygen outlet for attaching the oxygen tubing, a monitor, a flow meter knob, a flow meter , and a standard on/off rocker type power switch	JMC5A Ni oxygen concentrator is made up of mainframe and flowmeter. The front panel of the device contains the controls and indicators. These include a standard barb fitting for attaching the oxygen tubing, the adjustable flow meter, a power light indicator, an elapsed time meter, and a standard on/off rocker type power switch.	Similar Note 2
Filters	Cabinet, out HEPA，Compressor inlet	Cabinet, out HEP，Compressor inlet	Same

Table 1: Comparison between model OX-5A and K230969			
Elements of Comparison	**Subject Device**	**Primary Predicate Device**	**Verdict**
Oxygen sensor	Model: OCS-3FL-1.2	Model: OXY-III-B, Gasboard-7500K	Different Note 3
Compressor	Model: YQC280	Model: 1120-2-1-3, 1121-1-2-1(100046	Different
Material of main components	Components and associated materials which contact the gas pathway to the patient: Filter-Filter paper：HEPA Silencer: PA6+GF35% Silicone tube: Silicone Compressor: AL ADC12,PTFE, Stainless steel, Brass; Sieve beds: Brass, PA6+GF30%,Aluminum, SWP, Nonwoven fabric, Silicones, PA6+30%GF, Zeolites & Mineral Biner, Brass; Solenoid valve: ABS, Silicones, SWP, Brass; Regulator: ABS, Silicones, Carbon steel; Flowmeter: ABSM Brass, Silicones; OCI: ABS; Bacterial filter: PP	Components and associated materials which contact the gas pathway to the patient: filter-High efficiency particulate air (HEPA) filter paper; Compressor- ASM; Heat exchanger-Aluminum; Valve assembly-Aluminum; Molecular sieve Module-Li2O·Al2O3·(2.2±0.2) SiO2·9/2H2O; Silicone tube- Silicone; Product tank-ABS; Bacillifilter- Non-woven polyester fiber; Flow meter-Acrylic; Check valve-Fluororubber; Oxygen outlet connector-Copper; Commute valve-Fluororubber; Muffler, Enclosure, Base-ABS;	Similar Note 4

Table 1: Comparison between model OX-5A and K230969			
Elements of Comparison	**Subject Device**	**Primary Predicate Device**	**Verdict**
	Check valve : ABS, SWP, Silicones; Oxygen outlet: Brass	Transformer, AC fan, Wheel, Control panel, Power cord-ASM; PCB- Flame Retardant Copper Clad Epoxy E Glass Cloth Laminate	
Power supply	AC 110 V, 60 Hz	AC120V, 60Hz;	Similar Note 5
Oxygen concentration	93%±3%	93%±3%	Same
Oxygen flow	0.5 to 5 L/min	0.5~5 L/min	Same
Outlet pressure	8.5±0.5psi (58.6±3kPa)	38kPa±5kPa	Similar Note 6
Noise	Average A- weighted sound pressure level: ≤45dB Sound power level: ≤55dB	Sound level: ≤ 50.5dB (A); Acoustic power level: 58.5dB (A)	Similar Note 7
Net weight	15.3kg	16.1kg	Different Note 8
Dimension	342mm(L) x368mm(W) x572mm(H)	330×260×540(mm)	Different Note 8
Electrical classification	Class II Type BF	Class II Type BF	Same
Alarm	● Low Oxygen concentration alarm; ● Power failure alarm; ● High temperature alarm ● Compressor failure alarm ● Obstruction of gas pathways prompt ● Oxygen generation means failure alarm ● Pressure failure alarm	● Start-up fail alarm ● Low oxygen concentration alarm ● Power supply failure alarm ● Pressure failure alarm	Similar Note 9

Table 1: Comparison between model OX-5A and K230969			
Elements of Comparison	**Subject Device**	**Primary Predicate Device**	**Verdict**
Mode of operation	Continuous duty	Continuous duty	Same
Normal operation ambient	Temperature 5℃ to 40℃ Humidity 15% to 80% Atmospheric pressure 80~106kpa (11.6~15.4psi) Altitude: less than 2,000 m (6,500 feet).	Temperature range: 5℃ ~ 40℃ (41℉ ~104℉) Relative humidity: ≤80% Atmospheric pressure: 86kPa ~ 106kPa (12.47psi~15.37psi) 1828 meter (5997 feet) height above sea level	Similar Note 10
Storage and transport ambient	Temperature -20℃ to 55℃ Humidity 15% to 93% Atmospheric pressure 50~106kPa (7.3~15.4 psi)	Temperature Range: 0℃~+55℃ (32℉~+131℉) Relative Humidity Range: 10%~90% Atmospheric pressure: 70kPa ~ 106kPa (10.2psi~15.37psi)	Similar Note 10
Software control	Yes	Yes	Same
Patient interface type	Visual, direct contact type patient interface	Visual, direct contact type patient interface	Same

Comparison in Detail(s):

Note 1:

The intended patient population of predicate device is adults. And the intended patient of subject device is patients above 22 years old. Therefore, the intended use and indications of subject device is same as the predicate device.

Note 2:

Though the structure and main components of subject device is a litter different from predicate device. The subject device meets the requirement of IEC 60601-1, ISO 80601-2-69. Therefore, the slightly difference will not raise safety or effectiveness issues.

Note 3:

The oxygen sensor and compressor are different from those used for predicate device. The subject device meets the requirement of IEC 60601-1, ISO 80601-2-69, and ISO 18562 series standards. Therefore, the difference will not raise safety or effectiveness issues.

Note 4:
Though there is difference of the materials which contact the gas pathway to patient between the subject device and predicate device, the subject device meets the requirement of ISO 18562-1, ISO 18562-2 and ISO 18562-3. Therefore, the difference will not raise safety issues.

Note 5:
Though the power supply of subject device is a litter different from predicate device, the subject device meets the requirement of IEC 60601-1 and IEC 60601-1-11, the slightly difference will not raise safety or effectiveness issues.

Note 6:
The outlet pressure of subject device is a litter higher than predicate device, but the subject device meets the requirement of ISO 80601-2-69. So, the difference will not raise safety or effectiveness issues.

Note 7:
The noise of subject device is lower than the predicate device, and it meets the requirement of ISO 80601-2-69. So, the difference will not raise safety issues.

Note 8:
The net weight and dimension of subject device are different from predicate device. The difference will affect the effectiveness and safety of the subject device.

Note 9:
There are more alarms for subject device, and the setting of alarm meet the requirement of ISO 80601-2-69. So, the difference will not affect the effectiveness and safety of the subject device.

Note 10:
The operation, storage and transport ambient are a litter different from predicate device, but the subject device meets the requirement of IEC 60601-1 and IEC 6061-1-11 and ISO 80601-2-69. So, the difference will not affect the effectiveness and safety of the subject device.

Table 2: Comparison between OX-5C and K230969

Elements of Comparison	Subject Device	Primary Predicate Device	Verdict
Company	Oxytek Medical Technology Co.,Ltd.	Jiangsu Jumao X-Care Medical Equipment Co., Ltd.	--
Trade Name	Oxygen Concentrator	Portable oxygen generator	--
Model	OX-5C	JMC5A Ni	--
510(k) Number	K252965	K230969	--
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 oxygen concentrator is intended to provide	The JUMAO Oxygen Concentrator is intended to	Same Note 11

Table 2: Comparison between OX-5C and K230969			
Elements of Comparison	**Subject Device**	**Primary Predicate Device**	**Verdict**
	supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life. The intended patient should above 22 years old.	provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.	
Intended patient population	The device is intended for use in adults.	The device is intended for use in adults.	Same
Structure and main components	The Oxygen Concentrator is made up of mainframe and flowmeter. The front panel of the device contains the controls and indicators. These include a oxygen outlet for attaching the oxygen tubing, a monitor, a flow meter knob, a flow meter , and a standard on/off rocker type power switch	JMC5A Ni oxygen concentrator is made up of mainframe and flowmeter. The front panel of the device contains the controls and indicators. These include a standard barb fitting for attaching the oxygen tubing, the adjustable flow meter, a power light indicator, an elapsed time meter, and a standard on/off rocker type power switch.	Similar Note 12
Filters	Cabinet, out HEPA，Compressor inlet	Cabinet, out HEP，Compressor inlet	Same
Oxygen sensor	Model: OCS-3FL-1.2	Model: OXY-III-B, Gasboard-7500K	Different Note 13
Compressor	Model: YQC280	Model: 1120-2-1-3, 1121-1-2-1(100046	Different
Material of main components	Components and associated materials which contact the gas pathway to the patient: Filter-Filter paper：HEPA	Components and associated materials which contact the gas pathway to the patient: filter-High efficiency particulate air (HEPA)	Similar Note 14

Table 2: Comparison between OX-5C and K230969			
Elements of Comparison	**Subject Device**	**Primary Predicate Device**	**Verdict**
	Silencer: PA6+GF35% Silicone tube: Silicone Compressor: AL ADC12,PTFE, Stainless steel, Brass; Sieve beds: Brass, PA6+GF30%,Aluminum, SWP, Nonwoven fabric, Silicones, PA6+30%GF, Zeolites & Mineral Biner, Brass; Solenoid valve: ABS, Silicones, SWP, Brass; Regulator: ABS, Silicones, Carbon steel; Flowmeter: ABSM Brass, Silicones; OCI: ABS; Bacterial filter: PP Check valve : ABS, SWP, Silicones; Oxygen outlet: Brass	filter paper; Compressor- ASM; Heat exchanger-Aluminum; Valve assembly-Aluminum; Molecular sieve Module- $Li_2O \cdot Al_2O_3 \cdot (2.2 \pm 0.2) SiO_2 \cdot 9/2H_2O$; Silicone tube- Silicone; Product tank-ABS; Bacillifilter- Non-woven polyester fiber; Flow meter-Acrylic; Check valve-Fluororubber; Oxygen outlet connector-Copper; Commute valve-Fluororubber; Muffler, Enclosure, Base-ABS; Transformer, AC fan, Wheel, Control panel, Power cord-ASM; PCB- Flame Retardant Copper Clad Epoxy E Glass Cloth Laminate	
Power supply	AC 110 V, 60 Hz	AC120V, 60Hz;	Similar Note 15

Table 2: Comparison between OX-5C and K230969			
Elements of Comparison	**Subject Device**	**Primary Predicate Device**	**Verdict**
Oxygen concentration	93%±3%	93%±3%	Same
Oxygen flow	0.5 to 5 L/min	0.5~5 L/min	Same
Outlet pressure	8.5±0.5psi (58.6±3kPa)	38kPa±5kPa	Similar Note 16
Noise	Average A- weighted sound pressure level: ≤45dB Sound power level: ≤55dB	Sound level: ≤ 50.5dB (A); Acoustic power level: 58.5dB (A)	Similar Note 17
Net weight	14kg	16.1kg	Different Note 18
Dimension	332mm(L) x327mm(W) x483mm(H)	330×260×540(mm)	Different Note 18
Electrical classification	Class II Type BF	Class II Type BF	Same
Alarm	● Low Oxygen concentration alarm; ● Power failure alarm; ● High temperature alarm ● Compressor failure alarm ● Obstruction of gas pathways prompt ● Oxygen generation means failure alarm ● Pressure failure alarm	● Start-up fail alarm ● Low oxygen concentration alarm ● Power supply failure alarm ● Pressure failure alarm	Similar Note 19
Mode of operation	Continuous duty	Continuous duty	Same
Normal operation ambient	Temperature 5℃ to 40℃ Humidity 15% to 80% Atmospheric pressure 80~106kpa (11.6~15.4psi) Altitude: less than 2,000 m (6,500 feet).	Temperature range: 5℃ ~ 40℃ (41℉ ~104℉) Relative humidity: ≤80% Atmospheric pressure: 86kPa ~ 106kPa (12.47psi~15.37psi) 1828 meter (5997 feet) height above sea level	Similar Note 20

Table 2: Comparison between OX-5C and K230969			
Elements of Comparison	**Subject Device**	**Primary Predicate Device**	**Verdict**
Storage and transport ambient	Temperature -20℃ to 55℃ Humidity 15% to 93% Atmospheric pressure 50~106kPa (7.3~15.4 psi)	Temperature Range: 0℃~+55℃ (32℉~+131℉) Relative Humidity Range: 10%~90% Atmospheric pressure: 70kPa ~ 106kPa (10.2psi~15.37psi)	Similar Note 20
Software control	Yes	Yes	Same
Patient interface type	Visual, direct contact type patient interface	Visual, direct contact type patient interface	Same

Comparison in Detail(s):

Note 11:

The intended patient population of predicate device is adults. And the intended patient of subject device is patients above 22 years old. Therefore, the intended use and indications of subject device is same as the predicate device.

Note 12:

Though the structure and main components of subject device is a litter different from predicate device. The subject device meets the requirement of IEC 60601-1, ISO 80601-2-69. Therefore, the slightly difference will not raise safety or effectiveness issues.

Note 13:

The oxygen sensor and compressor are different from those used for predicate device. The subject device meets the requirement of IEC 60601-1, ISO 80601-2-69, and ISO 18562 series standards. Therefore, the difference will not raise safety or effectiveness issues.

Note 14:

Though there is difference of the materials which contact the gas pathway to patient between the subject device and predicate device, the subject device meets the requirement of ISO 18562-1, ISO 18562-2 and ISO 18562-3. Therefore, the difference will not raise safety issues.

Note 15:

Though the power supply of subject device is a litter different from predicate device, the subject device meets the requirement of IEC 60601-1 and IEC 60601-1-11, the slightly difference will not raise safety or effectiveness issues.

Note 16:

The outlet pressure of subject device is a litter higher than predicate device, but the subject device meets the requirement of ISO 80601-2-69. So, the difference will not raise safety or effectiveness issues.

Note 17:
The noise of subject device is lower than the predicate device, and it meets the requirement of ISO 80601-2-69. So, the difference will nor raise safety issues.

Note 18:
The net weight and dimension of subject device are different from predicate device. The difference will affect the effectiveness and safety of the subject device.

Note 19:
There are more alarms for subject device, and the setting of alarm meet the requirement of ISO 80601-2-69. So, the difference will not affect the effectiveness and safety of the subject device.

Note 20:
The operation, storage and transport ambient are a litter different from predicate device, but the subject device meets the requirement of IEC 60601-1 and IEC 6061-1-11 and ISO 80601-2-69. So, the difference will not affect the effectiveness and safety of the subject device.

Final Conclusion:
The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device K230969.

8. Date of the summary prepared: April 17, 2026