December 22, 2025

Qingdao Kingon Medical Science and Technology Co., Ltd
Zhang Benrong
Official Correspondent
Room 301-302, No.15 Hancheng Road, Qingdao Free Trade Zone
24th Building, NO. 252 Yanhe Road, Huangdao
Qingdao, Shandong 266510
China

Re: K251764
Trade/Device Name: Oxygen Concentrator-P2-O5E
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: November 24, 2025
Received: November 24, 2025

Dear Zhang Benrong:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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.	K251764

Please provide the device trade name(s).

Oxygen Concentrator (P2-O5E)

Please provide your Indications for Use below.

The oxygen concentrator P2-O5E is intended to provide supplemental low flow oxygen. The device is not intended for life support, nor does it provide any patient monitoring capabilities. This device is for adults only.

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

I. Date of the Summary Prepared: 20/12/2025

II. Administrative Information

Manufacturer information	**Establishment registration number**	3014777423
	Owner/Operator Number	10061814
	Name	Qingdao Kingon Medical Science and Technology Co., Ltd.
	Address	Room 301-302, No.15 Hancheng Road, Qingdao Free Trade Zone, Shandong, China, 266555
	Contact Person	**Name:** Benrong Zhang **Address**: Room 301-302, No.15 Hancheng Road, Qingdao Free Trade Zone, Shandong, China, 266555 **TEL:** +86-18565833539 **FAX:** +86 532 58792324 **Email:** augus@kingonmed.com

III. Device Information

Type of 510(k)	Traditional 510K
Prior submission	K251764
Common Name	Generator, Oxygen, Portable
Classification name	Portable oxygen generator
Trade Name	Oxygen Concentrator (Model: P2-O5E)
Review panel	Anesthesiology
Product code	CAW
Regulation Number	868.5440
Regulation Class	2

IV. Predicate Device Information

Device name	DOGS-S Deployable Oxygen Generation System-Small
510(k) number	K150930
Product code	CAW

V. Device Description and Indications for Use

Device description: The oxygen concentrator P2-O5E is intended to provide supplemental low flow oxygen. The device is not intended for life support, nor does it provide any patient monitoring capabilities. The oxygen concentrator consists of two parts: an oxygen concentrator and accessories. The oxygen concentrator is composed of compressor, fans, solenoid valves, molecular sieve beds, circuit control system, heat dissipation system, and a flow control device. Accessories include power cord, air intake filter box, air intake filter cotton.

Indications for Use: The oxygen concentrator P2-O5E is intended to provide supplemental low flow oxygen. The device is not intended for life support, nor does it provide any patient monitoring capabilities. This device is for adults only.

VI. Principle of Operation

Oxygen concentrator refers to the device that uses the principle of molecular sieve pressure swing adsorption to improve the oxygen concentration by adsorbing nitrogen and other gas components.

When the device is working, compressed air is injected into a sealed adsorption tower containing molecular sieve, causing the pressure inside the adsorption tower to increase. The molecular sieve in the tower absorb a large amount of nitrogen from the compressed air as the environmental pressure increases, while the oxygen in the compressed air still exists in a gaseous form and is collected through a certain pipeline. This process is commonly referred to as the “adsorption” process. When the molecular sieve in the container adsorb nitrogen to the critical state of adsorption saturation, the adsorption tower is blown and depressurized. As the environmental pressure decreases, the ability of the molecular sieve to adsorb nitrogen decrease, and nitrogen is released from inside the molecular sieve and discharged as waste gas. This process is commonly referred to as “desorption”. In order to ensure the continuous and stable output of oxygen, the oxygen concentrator mostly uses two (or more) molecular sieve adsorption towers, which are controlled by rotating separation valves, so that one adsorption tower is in the adsorption process while the other is in the desorption process, and the two work alternately to complete the continuous oxygen production process. The ultrasonic oxygen concentration sensor realizes the detection of oxygen concentration.

VII. Comparison with Predicate Device

DOGS-S Deployable Oxygen Generation System-Small manufactured by AirSep Corporation was selected for comparison. See the following table for details of comparison:

ID	Items	Predicate Device (K150930)	Device to be submitted for 510k	Remark
1	Product Code	CAW	CAW	Same
2	Regulation No.	21 CFR 868.5440	21 CFR 868.5440	Same
3	Class	II	II	Same
4	Product Name	DOGS-S Deployable Oxygen Generation System-Small	Oxygen Concentrator (P2-O5E)	-
5	Model	-	P2-O5E	-
6	Indication for Use	The Deployable Oxygen Generator System – Small (DOGS-S) is intended for the administration of supplemental oxygen. This device is not intended for life support nor does it provide any patient monitoring capabilities. The system will be operated by trained personnel.	The oxygen concentrator P2-O5E is intended to provide supplemental low flow oxygen. The device is not intended for life support, nor does it provide any patient monitoring capabilities. This device is for adults only.	Note 1
7	Patient Interface	Nasal Cannula	Nasal Cannula	Same
8	Principle of operation	By means of molecular sieve	By means of molecular sieve	Same
9	Dimensions	Diameter:10”, height: 33”	41.5cm*24.1cm*60.5cm	Note 2

10	Weight	37 lbs. w/o battery	15.8 kg±0.5kg	Note 2
11	Oxygen Concentration	93% +/-3% USP	90%-3%/+6% at all settings	Note 3
12	Flow Rate	0.5 to 15 L/min continuous flow	0.5 L/min -5.0 L/min continuous flow	Note 4
13	Power Supply	AC Power (100-240 VAC, 50-60 Hz) Battery 674 Whr peak	AC Power (Input: 100-240 VAC, 50-60 Hz)	Note 5
14	Power Consumption	550 Watts @ 15LPM	500VA Max	Note 5
15	Software/Hardware	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor	Same
16	Acoustic Noise	<70dB(A)	≤ 60dB (A) (At maximum flow)	Note 6
17	Output pressure	10.0 psig nominal	4-7 PSI	Note 3
18	Alarms	Low Oxygen purity	Low oxygen concentration	Note 7
		O_2 Flow High or Low	Power supply failure technical alarm	
		Low power indicator (Battery)	Start-up period technical alarm	
		Unit malfunction	Unit malfunction	
19	Single Patient, Multi-use	Yes	Yes	Same
20	Patient Population	Adult	Adult	Same
21	Device Components	Host, battery pack / lithium ion, power cord, nasal cannula	Host, power cord	Note 8
22	Materials for Patient Contact Components	Panel: PET Main housing: PC+ABS	Panel: PET Main housing: PC+ABS	Same
23	Material of Filter	Chemical Fiber	Chemical Fiber	Same

24	Type of Electric Shock Protection	Class II	Class II	Same
25	Electromagnetic Compatibility	IEC 60601-1-2	IEC 60601-1-2	Same
26	Biocompatibility	Particulate Matter Testing Volatile Organic Compound Testing ISO 10993-1 Biological Evaluation of Medical Devices - Cytotoxicity - Sensitization - Irritation	ISO 18562-2 Particulate Matter Testing ISO 18562-3 Volatile Organic Compound Testing ISO 10993-5 Cytotoxicity ISO 10993-10 Sensitization ISO 19993-23 Irritation	Same
27	Electrical Safety	IEC 60601-1	IEC 60601-1	Same

Note:

1. ID 6

There is difference in indication for use between predicate device and subject device. However, the subject device has passed the IEC 60601-1:2005 /A1:2012/A2:2020 and ISO 80601-2-69:2020 test. Hence, the difference doesn't raise new questions of safety and effectiveness.

2. ID 9 and ID 10

Although the dimension and weight are different from the predicate device. However, the subject device has passed the IEC 60601-1:2005 /A1:2012/A2:2020 test. And compared to the predicate device, the subject device is lighter in weight and easier to move. Hence, the differences don't raise new questions of safety and effectiveness.

3. ID 11 and ID 17

The oxygen concentration of predicate device is 93% +/-3% USP and of subject device P2-O5E is 90%-3%/+6% at all settings. The output pressure of subject device P2-O5E is different from predicate device DOGS-S (K150930). These risks are mitigated by test tested according to ISO 80601-2-69:2020, therefore the differences don't raise new questions of safety and effectiveness.

4. ID 12

Both predicate device and subject device provide oxygen in continuous flow. The flow rate setting of predicate device is 0.5-15 L/min and of subject device P2-O5E is 0.5-5.0 L/min. The risk is mitigated by tests tested according to ISO 80601-2-69:2020, ISO 18562-2:2017, ISO 18562-3:2017, ISO 10993-5:2019, ISO 10993-10:2021, and ISO 10993-23:2021, therefore the difference does not raise new questions of safety and effectiveness.

5. ID 13 and ID 14

There are differences in power supply and power consumption between predicate device and subject device. The predicate device can be powered by AC power and battery, while the subject device can only be powered by AC power. The subject device cannot be powered by battery. However, the subject device has passed the ISO 80601-2-69:2020, IEC 60601-1:2005 /A1:2012/A2:2020, IEC 60601-1-2:2014/A1:2020. Hence, the differences don't raise new questions of safety and effectiveness.

6. ID 16

The acoustic noise of subject device P2-O5E is lower than predicate device DOGS-S (K150930). Since the subject device has been tested against ISO 80601-2-69:2020 and IEC 60601-1:2005/A1:2012/A2:2020, the difference of subject device doesn't raise new questions of safety and effectiveness.

7. ID 18

The subject device and the predicate device have difference in alarms information displayed. However, the subject device meets the requirements of the standard ISO 80601-2-69:2020 and IEC 60601-1-8:2006/A1:2012/A2:2020. In addition, performance testing and risk analysis has been conducted on the subject device. Hence, the difference of subject device doesn't raise new questions of safety and effectiveness.

8. ID 21

The subject device and the predicate device have difference in device components. However, the subject device meets the requirements of the standard ISO 80601-2-69:2020, IEC 60601-1:2005/A1:2012/A2:2020, IEC 60601-1-2:2014/A1:2020, IEC 60601-1-6:2010/A1:2013/A2:2020. In addition, risk analysis have been conducted on the subject device. Hence, the difference of subject device doesn’t raise new questions of safety and effectiveness.

VIII. Discussion of Non-Clinical Tests Performed for Safety and Effectiveness Are As Follows

This device has undergone basic safety and performance testing in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11 and ISO 80601-2-69. Biocompatibility related tests were conducted according to ISO 18562-1, ISO 18562-2, ISO 18562-3, ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-23. And software and lifespan related testing verification was conducted. See below table for details:

Standards	Standards Name
IEC 60601-1:2005/A1:2012/A2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014/A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2010/A1:2013/A2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8:2006/A1:2012/A2:2020	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
IEC 60601-1-11:2015/A1:2020	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
ISO 80601-2-69:2020	Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment
ISO 18562-1:2017	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 18562-3:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions

	of volatile organic compounds (VOCs)
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation

•Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted. The system complies with the IEC 60601-1, IEC 60601-1-8, IEC 60601-1-6, IEC 60601-1-11, and ISO 80601-2-69 standards for electrical safety and the IEC 60601-1-2 standard for EMC.

•Software Verification and Validation Testing

Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff.

•Biocompatibility Testing

Biocompatibility testing were conducted. The system complies with the ISO 18562-2, ISO 18562-3, ISO 18562-1, ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-23 for biocompatibility safety.

IX. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

X. Conclusions

The Oxygen Concentrator (Model: P2-O5E) has the similar characteristics as the cleared predicate device Deployable Oxygen Generator System - Small (DOGS-S). Bench testing contained in this submission supplied demonstrate that the differences existed between Oxygen Concentrator (Model: P2-O5E) and Deployable Oxygen Generator System - Small (DOGS-S) (K150930) do not raise any new questions of safety or effectiveness.

The non-clinical tests support the safety of the device and software verification and validation demonstrate that the Oxygen Concentrator (Model: P2-O5E) performs as

intended in the specified use conditions are same with predicate device. The performance tests demonstrate that the Oxygen Concentrator (Model: P2-O5E) performs comparably to the predicate device that is currently marketed for the same intended use. Thus, Oxygen Concentrator (Model: P2-O5E) is Substantially Equivalent (SE) to the predicate device.