June 3, 2022

Qingdao Kingon Medical Science and Technology Co., Ltd.
℅ You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd
RM.1711, Building K, NO.101 Science Ave International
Creative Valley
Guangzhou, Guangdong 510663
China

Re: K210371
Trade/Device Name: Portable Oxygen Concentrator, model: P2-E6
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: May 2, 2022
Received: May 2, 2022

Dear You Yijie:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210371

Device Name
Portable Oxygen Concentrator, model: P2-E6

Indications for Use *(Describe)*
The Portable Oxygen Concentrator, model: P2-E6 is intended to provide supplemental oxygen in a home, institutional, or travel environment.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K210371

1. Submitter's Information

Establishment Registration Information

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Date prepared: Jan. 14, 2021

2. Device Information

Trade Name:	Portable Oxygen Concentrator
Model:	P2-E6
Classification name:	Generator, Oxygen, Portable
Review panel:	Anesthesiology
Product code:	CAW
Regulation Class:	II
Regulation Number:	868.5440

3. Predicate Device Information

510(k) submitter/holder:	Oxus Inc.

510(K) Number:	K162433
Trade Name:	GCE Zen-O™ Portable Oxygen Concentrator
Model:	RS-00500
Classification name:	Generator, Oxygen, Portable
Review panel:	Anesthesiology
Product code:	CAW
Regulation Class:	II
Regulation Number:	868.5440

4. Device description

Portable Oxygen Concentrator, model: P2-E6 is a portable oxygen generator that is intended to release oxygen for respiratory therapy by means of physical means (a molecular sieve). It supplies a pulsed high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The P2-E6 is small, portable and may be used in home, institutional, or travel environment.

The portable oxygen concentrator consists of two parts: an oxygen concentrator and accessories. The oxygen concentrator is composed of compressor, battery, solenoid valve, molecular sieve, circuit control system, heat dissipation system, and a flow control device. Accessories include power adapters.

Principle of operation:

The device works by getting use of the molecular sieves character that the internal pressure of a sealed container containing of molecular sieve will increase when injecting air into it. At this time, the molecular sieve will absorb a lot of nitrogen in the air with the increasing of ambient pressure, while the oxygen in the air is still existed in gaseous form, then the oxygen are collected through some pipelines. When the nitrogen absorption process in the container reaches a certain level, then exhaust of the vacuum container and nitrogen will be released from molecular sieve with the ambient pressure decreases. It will detect when the user begins to take a breath and then delivers a pulsed volume of oxygen during the inhalation period. The volume of the oxygen pulse is dependent on the setting value.

5. Indications for Use

The Portable Oxygen Concentrator, model: P2-E6 is intended to provide supplemental oxygen in a home, institutional, or travel environment.

6. Summary of technological characteristics of device compared to the predicate device (K162433)

SE Comparisons	Subject device (Portable Oxygen Concentrator,	Primary predicate device	Discussion of difference

	model: P2-E6)	**(GCE Zen-O™ Portable Oxygen Concentrator, Model: RS-00500)**	
510K Number	/	**K162433**	**/**
Classification	21CFR 868.5440	21CFR 868.5440	**Same**
Product Code	CAW	CAW	**Same**
FDA Class	II	II	**Same**
Indications for Use	The Portable Oxygen Concentrator, model: P2-E6 is intended to provide supplemental oxygen in a home, institutional, or travel environment.	The Portable Oxygen Concentrator is intended to provide supplemental oxygen in a home, institutional, or travel environment.	**Same**
Model	P2-E6	RS-00500	**/**
Environment of Use	Home, institutional, or travel environment.	Home, institutional, or travel environment.	**Same**
Design	table type	table type	**Same**
Prescriptive	Yes	Yes	**Same**
Patient Population	Adult	Adult	**Same**
Material of Patient contact components	Wiring cover: PC+ABS Intake hood: PC+ABS Nozzle fitting: Aluminum alloy Button panel: PET Main housing: PC+ABS	Device enclosure, • Handle, • Battery, and • Interface panel.	**Different** (Discussion is indicated in D1)
Duration and type of contact	Type of contact: surface device; Duration: permanent (> 30 d);	Category: External communicating device Contact: Tissue Duration: A – Limited (≤ 24 h)	**Different** (Discussion is indicated in D2)
Complete list of all the biocompatibility tests performed	ISO 10993- 5 tested for Cytotoxicity; ISO 10993-10 tested for Sensitization and Irritation; ISO 18562-2 tested for Particulate matter; ISO 18562-3 tested for Volatile organic Compounds;	ISO 10993- 5 tested for Cytotoxicity; ISO 10993-10 tested for Sensitization and Irritation; Particulate Matter test Inorganic gases (Ozone, CO2, and CO) test	**Different** (Discussion is indicated in D3)
Single Patient, multi-use	Yes	Yes	**Same**
Patient Interface	Cannula Port	Cannula Port	**Same**
Technology	Pressure Swing Adsorption with molecular sieve	Pressure Swing Adsorption with molecular sieve	**Same**
Dimensions	6.30”H*3.35”W*8.70”L	6.6”H*8.3”w*12.3L	**Different** (Discussion is indicated in D4)

Weight	4.34lbs±0.07lbs (with standard battery)	10.25lbs with one 12 cell battery	**Different** (Discussion is indicated in D5)
Oxygen Concentration	90%-3%/+6% at all settings	87% - 96% at all settings	**Same**
Setting	adjustable in 1 increments from 1 to 6	adjustable in 0.5 increments from 1.0 to 6.0 in pulse mode	**Same**
Equivalent Flow rates	1.0 to 6.0 LPM from setting 1 to setting 6	1-6 LPM from setting 1 to settimg 6 in pulse mode	**Same**
Pulse mode bolus size	60mL per breath at setting 6 with 20BPM	66mL per breath at setting 6 with 20BPM	**Different** (Discussion is indicated in D6)
Principle of operation	by means of molecular sieve	by means of molecular sieve	**Same**
Filters	Input Filter, Patient Filter	Input Filter, Patient Filter	**Same**
Breath rate	10 - 40 Breath per minute	15 - 40 Breath per minute	**Different** (Discussion is indicated in D7)
User Interface	Buttons, LCD Display	Buttons, LCD Display	**Same**
Power requirements	AC adaptor: 100-240VAC ;50-60 Hz in，19VDC 5.26A out DC adaptor: 12 - 16V DC in，19V 6A out	AC adaptor: 100-240V AC(+/-10%) 50-60 Hz in, 24VDC, 6.25A out DC adaptor: 11.5 - 16V DC in, 19V, 7.9A out	**Different** (Discussion is indicated in D8)
Maximum oxygen discharge pressure	18.3 PSI (126KPa)	20.5 PSI	**Different** (Discussion is indicated in D9)
Inspiratory trigger sensitivity	-0.12cm/H20	-0.12cm/H20	**Same**
Software	Embedded	Embedded	**Same**
Acoustic Noise	49 dBA at 1.2 LPM	42 dBA at 2 LPM	**Different** (Discussion is indicated in D10)
Alarms	Battery empty	Battery empty	**Same**
	Low pressure	Low pressure	**Same**
	No pulse	No pulse	**Same**
	High Temp	High Temp	**Same**
	Compressor Failure	Compressor Failure	**Same**
	Fan Failure	Fan Failure	**Same**
	Low Flow	Low Flow	**Same**
	Low Battery	Low Battery	**Same**
	No Breath Detected	No Breath Detected	**Same**
	EEPROM Failure	EEPROM Failure	**Same**

Status Indicator	Flow rates	Flow rates	**Same**
	Battery Condition	Battery Condition	**Same**
	Alarms	Alarms	**Same**
Battery Duration	Up to 4.5hours at 1. 2 LPM	Approximately 4 hours at 2 LPM (pulse)	**Different** (Discussion is indicated in D11)
Operating Environment	Temperature: 41 to 104˚F (5 to 40˚C) Humidity: 10% to 90%, non-condensing Altitude: 0 to 10,000 ft. (0 to 3048 meters)	5-40˚C; Altitude:0-9000 ft; RH:5-93%	**Different** (Discussion is indicated in D12)
Shipping Storage	Temperature: -4 to 158˚F (-20 to 70˚C) Humidity: 5% to 90%, non-condensing Store in a dry environment	Temperature:-20 to 60˚C,Keep dry: Humidity:0-93%RH	**Different** (Discussion is indicated in D13)
Electrical Safety	AAMI ANSI ES 60601-1	AAMI ANSI ES60601-1	**Same**
electromagnetic compatibility	IEC 60601-1-2	IEC 60601-1-2	**Same**
Biocompatibility	4 VOC's less than ambient	4 VOC's less than ambient	**Same**
Standards Met	ANSI AAMI ES 60601- 1: 2005 / (R) 2012 and A1: 2012 IEC 60601-1-2: 2014 IEC 60601-1-11: 2015 IEC 60601-1-8: 2006+ A1:2012 ISO 80601-2-69: 2014 ISO 80601-2-67: 2014 ISO 18562-2: 2017 ISO 18562-3: 2017 IEC 62133: 2012 ISO 10993-5:2009 ISO 10993-10:2010	AAMI ANSI ES60601-1 IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-1-11 ISO 80601-2-67 ISO 80601-2-69 10993	**Different** (Discussion is indicated in D14)

The discussion of differences exist between the subject and predicate devices is listed in following:

D1: The subject device P2-E6 has been validated for Cytotoxicity though testing against ISO 10993- 5, for Sensitization and Irritation though testing against ISO 10993-10 tested, for Particulate matter though testing against ISO 18562-2, for Volatile organic Compounds though testing against ISO 18562-3 according to FDA Guidance-Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and standard ISO 18562-1 (First edition 2017-03) and all test results are positive , the difference of subject device with predicate device RS-00500 (K162433) do not raise new questions of safety and effectiveness.

D2: According to FDA Guidance-Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and standard ISO 18562-1 (First edition 2017-03), and with the duration is permanent (> 30 d)) and type of contact is surface device of the subject device P2-E6, we have conducted testing for Cytotoxicity though testing against ISO 10993- 5, for Sensitization and Irritation though testing against ISO 10993-10 tested, for Particulate matter though testing against ISO 18562-2, for Volatile organic Compounds though testing against ISO 18562-3 and all test results are positive, the difference of subject device with predicate device RS-00500 (K162433) do not raise new questions of safety and effectiveness.

D3: The subject device P2-E6 has been validated for Cytotoxicity though testing against ISO 10993- 5, for Sensitization and Irritation though testing against ISO 10993-10 tested, for Particulate matter though testing against ISO 18562-2, for Volatile organic Compounds though testing against ISO 18562-3 and all test results are positive. According to FDA Guidance-Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and standard ISO 18562-1 (First edition 2017-03), the biocompatibility endpoints should be considered for the subject device are Cytotoxicity, Sensitization and Irritation, Particulate matter, Volatile organic Compounds all of which are addressed though tested against ISO 10993- 5, ISO 10993-10, ISO 18562-2 and ISO 18562-3, the difference of subject device with predicate device RS-00500 (K162433) do not raise new questions of safety and effectiveness.

D4: The dimension of subject device is different with predicate device RS-00500 (K162433) will not affect the safety and effectiveness.

D5: The weight of subject device is different with predicate device RS-00500 (K162433) will not affect the safety and effectiveness.

D6: The Pulse mode bolus size of subject device P2-E6 is little smaller than predicate device RS-00500 (K162433), since the predicate device are safe and effectiveness, and the subject device also been tested against ISO 80601-2-69: 2014 and ISO 80601-2-67: 2014 with positive result, which means the subject device P2-E6 is also safe and effective as predicate device when used with this setting parameter and will not raise new questions of safety and effectiveness.

D7: The Breath rate of subject device P2-E6 is different with predicate device RS-00500 (K162433), since the subject device has been tested against ISO 80601-2-69: 2014 and ISO 80601-2-67: 2014 with positive result, therefore, the subject device P2-E6 is as safe and effective as the predicate device and the difference of subject device with predicate device RS-00500 (K162433) do not raise new questions of safety and effectiveness.

D8: The Power of subject device are different with predicate devices, the difference introduces risks mitigated by the electromagnetic compatibility and electrical safety testing in accordance with IEC 60601-1-2 and ANSI AAMI ES60601-1 provided in this submission, therefore the difference does not raise new questions of safety and effectiveness.

D9: The Maximum oxygen discharge pressure of subject device P2-E6 is different with predicate device RS-00500 (K162433), since the subject device has been tested against ISO 80601-2-69: 2014 and ISO 80601-2-67: 2014 with positive result, the difference of subject device with predicate device RS-00500 (K162433) do not raise new questions of safety and effectiveness.

D10: The Acoustic Noise of subject device P2-E6 is litter bigger than predicate device RS-00500 (K162433), since the subject device P2-E6 has been tested against ISO 80601-2-69: 2014 and ANSI AAMI

ES60601-1 with positive results, the difference of subject device with predicate device RS-00500 (K162433) do not raise new questions of safety and effectiveness.

D11: The subject device P2-E6 equipped with longer Battery duration than predicate device RS-00500 (K162433), the difference introduces risks mitigated by the electromagnetic compatibility, electrical safety and battery safety testing in accordance with IEC 60601-1-2, ANSI AAMI ES60601-1 and IEC 62133 provided in this submission, therefore the difference do not raise new questions of safety and effectiveness.

D12: The operating condition of subject device are different with predicate device RS-00500 (K162433), the difference introduce risks mitigated by testing in accordance with IEC 60601-1-11 and ANSI AAMI ES60601-1 provided in this submission, therefore the difference do not raise new questions of safety and effectiveness.

D13: The Shipping Storage of subject device P2-E6 is different with predicate device RS-00500 (K162433), since the Shipping Storage of subject device had been verified with positive result (Package Verification Test Report), therefore the difference of subject device with predicate device RS-00500 (K162433) do not raise new questions of safety and effectiveness.

D14: The Standards Met. of subject device P2-E6 is different with predicate device RS-00500 (K162433), the difference of subject device with Primary predicate device RS-00500 (K162433) do not raise new questions of safety and effectiveness.

7. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES60601-1, IEC 60601-1-11 for safety, IEC 60601-1-2 for electromagnetic compatibility, ISO 80601-2-69: 2014 and ISO 80601-2-67: 2014 for performance and IEC 62304 for software verification are complied. See below table for details:

Standards	Standards Name
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2: 2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
IEC 60601-1-11: 2015	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
IEC 60601-1-8: 2006+ A1:2012	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: 2014	Medical electrical equipment. Particular requirements for the basic safety and essential performance of oxygen concentrator equipment
ISO 80601-2-67: 2014	Medical electrical equipment. Particular requirements for basic safety and essential performance of oxygen-conserving equipment
ISO 18562-2: 2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
ISO 18562-3: 2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications. Tests for emissions of volatile organic compounds (VOCs)
IEC 62133: 2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
IEC 62304:2006+A1:2015	Medical device software - Software life cycle processes

- **Electrical safety and electromagnetic compatibility (EMC)**
  Electrical safety and EMC testing were conducted on the subject device P2-E6. The system complies with the AAMI ANSI ES60601-1, IEC 60601-1, IEC 60601-1-8, IEC 60601-1-11, ISO 80601-2-67, 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, May 2005.

  Software Description:
  The software for this device was considered as a “moderate” level of concern, since a failure or latent flaw in the software could result in Minor Injury, either to a patient or to a user of the device. The software of the system, on the whole, is accountable for the system scheduler of the device, including fulfilling alarm task, beep task, detect task, display task, monitor task, startup task, breath task, as well as dealing with USART1-interrupt, USART2-interrupt, RTC-interrupt, WDT-interrupt, and controlling the sensor module.

  ➢ Programming language
  STMicroelectronics and Texas Instruments.

  ➢ Hardware platform
  a) Applicable Device Name: Portable Oxygen Concentrator

b) Applicable model: P2-E6
c) Micro-controller used: STM32F103RCT6, STM32F103C8T6, MSP430G2755
d) ROM Size: STM32F103RCT6 - 256K, STM32F103C8T6 - 64K, MSP430G2755 - 32K
e) RAM Size: STM32F103RCT6 - 48K, STM32F103C8T6 - 20K, MSP430G2755 -4K
f) Software Release Version Number: Keil uVision5 V5.25.20, IRA for 430 V7.12.1

8. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

9. Conclusions

The Portable Oxygen Concentrator, model P2-E6, have the same intended use and similar characteristics as the cleared predicate device RS-00500 (K162433). Moreover, bench testing contained in this submission supplied demonstrate that the differences existed between P2-E6 and RS-00500 (K162433) do not raise any new questions of safety or effectiveness.

The non-clinical tests support the safety of the device and the hardware and software verification and validation demonstrate that the Portable Oxygen Concentrator, model P2-E6 performs as intended in the specified use conditions are same with predicate device. The performance tests demonstrate that the Portable Oxygen Concentrator, model P2-E6 performs comparably to the predicate device that is currently marketed for the same intended use. Thus, the Portable Oxygen Concentrator, model P2-E6 is Substantially Equivalent (SE) to the predicate device.