June 22, 2023

Qingdao Kingon Medical Science and Technology Co., Ltd.
Zhang Benrong
Technical Supervisor
RM.1711, Building K, NO.101 Science Ave International
Creative Valley
Qingdao Free Trade Zone, Shandong 266555
China

Re: K223379
Trade/Device Name: Portable Oxygen Concentrator (Model: P2-E7, P2-E)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: May 24, 2023
Received: May 24, 2023

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 (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 and Part 809); 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,

Ting Song -S

For
James J. Lee, Ph.D.
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)*
K223379

Device Name
Portable Oxygen Concentrator (Model: P2-E7, P2-E)

Indications for Use *(Describe)*
The Portable Oxygen Concentrator (Model: P2-E7, P2-E) 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 as required by section 807.92(c)

I. Date of the summary prepared: 10/30/2022

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 HanchengRoad, Qingdao Free Trade Zone, Shandong, China, 266555
	Contact Person	**Name:** Benrong Zhang **Address**: Room 301-302, No.15 HanchengRoad, Qingdao Free Trade Zone, Shandong, China, 266555 **TEL:** +86-18565833539 **FAX:** +86 532 58792324 **Email:** augus@kingonmed.com
Submission Correspondent	Contact Person	**Name:** Tracy Nanan **Address**: Room 301-302, No.15 HanchengRoad, Qingdao Free Trade Zone, Shandong, China, 266555 **TEL:** +86-18565833539 **FAX:** +86 532 58792324 **Email:** ptg2022ptg@163.com

III. Device Information

Type of 510(k)	Special 510(k): Device Modification
Prior submission	No prior submission
Common Name	Generator, Oxygen, Portable
Classification name	Portable oxygen generator
Trade Name	Portable Oxygen Concentrator (Model: P2-E7, P2-E)
Review panel	Anesthesiology

Product code	CAW
Regulation Number	868.5540
Regulation Class	2

IV. Predicate Device Information

Common Name	Generator, Oxygen, Portable
Classification name	Portable oxygen generator
Trade Name	Portable Oxygen Concentrator, model: P2-E6
Review panel	Anesthesiology
Product code	CAW
Regulation Number	868.5540
Regulation Class	2

V. Device description

Portable Oxygen Concentrator (Model: P2-E7, P2-E) 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 Portable Oxygen Concentrator 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.

Model difference: The only different between model P2-E7 and P2-E is that P2-E7 has biggest output oxygen flow of 1.4L/min (at 7 gears) and P2-E has biggest output oxygen flow of 1.0L/min (at 5 gears).

VI. Principle of operation

Both model P2-E7 and P2-E has the same principle of operation. The portable oxygen concentrator 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.

VII. Indications for Use

The Portable Oxygen Concentrator (Model: P2-E7, P2-E) is intended to provide supplemental oxygen in a home, institutional, or travel environment.

VIII. Comparison with predicate device

ID	Comparison Items	Subject device	Predicate device	Comparison
1.	510K Number	/	K210371	/
2.	Manufacturer	Qingdao Kingon Medical Science and Technology Co., Ltd.	Qingdao Kingon Medical Science and Technology Co., Ltd.	Same
3.	Device name	Portable Oxygen Concentrator	Portable Oxygen Concentrator	/
4.	Model	P2-E7, P2-E	P2-E6	/
5.	Classification	21CFR 868.5440	21CFR 868.5440	Same
6.	Product Code	CAW	CAW	Same
7.	FDA Class	II	II	Same
8.	Indications for Use	The Portable Oxygen Concentrator (Model: P2-E7, P2-E) is intended to provide supplemental oxygen in a home, institutional, or travel environment.	The Portable Oxygen Concentrator, model: P2-E6 is intended to provide supplemental oxygen in a home, institutional, or travel environment.	Same
9.	Environment of Use	Home, institutional, or travel environment.	Home, institutional, or travel environment.	Same
10.	Design	table type	table type	Same
11.	Prescriptive	Yes	Yes	Same
12.	Patient Population	Adult	Adult	Same

13.	Material of Patient contact components	Wiring cover: PC+ABS Intake hood: PC+ABS Nozzle fitting: Aluminum alloy Button panel: PET Main housing: PC+ABS	Wiring cover: PC+ABS Intake hood: PC+ABS Nozzle fitting: Aluminum alloy Button panel: PET Main housing: PC+ABS	Same
14.	Duration and type of contact	Type of contact: surface device; Duration: permanent (> 30 d);	Type of contact: surface device; Duration: permanent (> 30 d);	Same
15.	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; ISO 18562-2 tested for Particulate matter; ISO 18562-3 tested for Volatile organic Compounds;	Same
16.	Single Patient, multi-use	Yes	Yes	Same
17.	Patient Interface	Cannula Port	Cannula Port	Same
18.	Technology	Pressure Swing Adsorption with molecular sieve	Pressure Swing Adsorption with molecular sieve	Same
19.	Dimensions	6.30”H*3.35”W*8.70”L	6.30”H*3.35”W*8.70”L	Same
20.	Weight	4.34lbs±0.07lbs (with standard battery)	4.34lbs±0.07lbs (with standard battery)	Same
21.	Oxygen Concentration	90%-3%/+6% at all settings	90%-3%/+6% at all settings	Same
22.	Setting	P2-E7: adjustable in 1 increments from 1 to 7. P2-E: adjustable in 1 increments from 1 to 5.	adjustable in 1 increments from 1 to 6	Different (See below note ID_22)
23.	Pulse mode bolus size	P2-E7: 50mL per breath at setting 5 with 20BPM P2-E: 50mL per breath at setting 5 with 20BPM	50mL per breath at setting 5 with 20BPM	Same
24.	Principle of operation	by means of molecular sieve	by means of molecular sieve	Same
25.	Filters	Input Filter, Patient Filter	Input Filter, Patient Filter	Same
26.	Breath rate	10 - 40 Breath per minute	10 - 40 Breath per minute	Same
27.	User Interface	Buttons, LCD Display	Buttons, LCD Display	Same
28.	Power requirements	AC adaptor: 100-240VAC ;50-60 Hz in，19VDC 5.26A out	AC adaptor: 100-240VAC ;50-60 Hz in，19VDC 5.26A out	Same

		DC adaptor: 12 - 16V DC in，19V 6A out	DC adaptor: 12 - 16V DC in，19V 6A out	
29.	Maximum oxygen discharge pressure	P2-E7: 20.6 PSI (142KPa) P2-E: 20.9 PSI (144KPa)	18.3 PSI (126KPa)	Different (See below note ID_29)
30.	Inspiratory trigger sensitivity	-0.12cm/H20	-0.12cm/H20	Same
31.	Software	Embedded	Embedded	Same
32.	Acoustic Noise	P2-E7: 58.8 dBA at 1.4 LPM P2-E: 52.0 dBA at 1.0 LPM	58.2 dBA at 1.2 LPM	Different (See below note ID_32)
33.	Alarms	Battery empty	Battery empty	Same
34.		Low pressure	Low pressure	Same
35.		No pulse	No pulse	Same
36.		High Temp	High Temp	Same
37.		Compressor Failure	Compressor Failure	Same
38.		Fan Failure	Fan Failure	Same
39.		Low Flow	Low Flow	Same
40.		Low Battery	Low Battery	Same
41.		No Breath Detected	No Breath Detected	Same
42.		EEPROM Failure	EEPROM Failure	Same
43.	Status Indicator	Flow rates	Flow rates	Same
44.		Battery Condition	Battery Condition	Same
45.		Alarms	Alarms	Same
46.	Battery Duration	P2-E7: Up to 4.5 hours at 0.21 LPM P2-E: Up to 4.5 hours at 0.21 LPM	Up to 4.5 hours at 0.21 LPM	Same
47.	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)	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)	Same
48.	Shipping Storage	Temperature: -4 to 158°F (-20 to 70°C) Humidity: 5% to 90%, non-condensing Store in a dry environment	Temperature: -4 to 158°F (-20 to 70°C) Humidity: 5% to 90%, non-condensing Store in a dry environment	Same
49.	Electrical Safety	AAMI ANSI ES 60601-1	AAMI ANSI ES 60601-1	Same

50.	electromagnetic compatibility	IEC 60601-1-2	IEC 60601-1-2	Same
51.	Biocompatibility	4 VOC's less than ambient	4 VOC's less than ambient	Same
52.	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	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	Same

Note:

ID_22: The max setting of subject device P2-E7 is 7 and of subject device P2-E is 5 while the predicate device is 6, the extra setting 7 of P2-E7 introduce risks of increased output flow and increased Emission of particulate matter of gas pass way, those risks are mitigated by tests tested according to ISO 80601-2-69: 2014, ISO 80601-2-67: 2014 and ISO 18562-2: 2017, therefore the difference does not raise new questions of safety and effectiveness.

ID_29: The Maximum oxygen discharge pressure of subject device P2-E7 and P2-E is different with predicate device P2-E6 (K210371), since the subject device has been tested against ISO 80601-2-69: 2014 with positive result, the difference of subject device with predicate device RS-00500 (K162433) do not raise new questions of safety and effectiveness.

ID_32: The Acoustic Noise of subject device P2-E7 is litter bigger than predicate device P2-E6 (K210371) and subject device P2-E is litter smaller than predicate device P2-E6 (K210371), since the subject device P2-E7 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 P2-E6 (K210371) do not raise new questions of safety and effectiveness.

IX. 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-E7, P2-E
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

X. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

XI. Conclusions

The Portable Oxygen Concentrator (Model: P2-E7, P2-E) have the same intended use and similar characteristics as the cleared predicate device Portable Oxygen Concentrator, model: P2-E6. Moreover, bench testing contained in this submission supplied demonstrate that the differences existed between Portable Oxygen Concentrator (Model: P2-E7, P2-E) and Portable Oxygen Concentrator, model: P2-E6 (K210371) 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-E7, P2-E) performs as intended in the specified use conditions are same with predicate device. The performance tests demonstrate that the Portable Oxygen Concentrator (Model: P2-E7, P2-E) performs comparably to the predicate device that is currently marketed for the same intended use. Thus, Portable Oxygen Concentrator (Model: P2-E7, P2-E) is Substantially Equivalent (SE) to the predicate device.