October 18, 2023

Qingdao Kingon Medical Science and Technology Co., Ltd.
Yanmei Jiao
Certification Engineer
24th Building, NO. 252 Yanhe Road
Huangdao, Qingdao, Shandong 266555
China

Re: K230702
Trade/Device Name: Portable Oxygen Concentrator (Model: P2-S4, P2-S3,P2-K4,P2-K3)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: May 31, 2023
Received: May 31, 2023

Dear Yanmei Jiao:

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.

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 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)*

Device Name
Portable Oxygen Concentrator (Model: P2-K3, P2-K4,P2-S3,P2-S4)

Indications for Use *(Describe)*
The Portable Oxygen Concentrator (Model: P2-K4,P2-K3,P2-S4, P2-S3) is intended to provide supplemental oxygen in a home, institutional, or travel environment.
It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Portable Oxygen Concentrator(Model:P2-K4,P2-K3,P2-S4,P2-S3) is small, portable and may be used in home, institution and various mobile environments. However, there is not any type of humidifier that is suitable for use with this device because of its pulse dose delivery mode.

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: 15/08/2023

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
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III. Device Information

Type of 510(k)	Traditional 510K
Prior submission	No prior submission
Common Name	Generator, Oxygen, Portable
Classification name	Portable oxygen generator
Trade Name	Portable Oxygen Concentrator

	(Model:P2-K4,P2-K3,P2-S4,P2-S3)
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-K4,P2-K3,P2-S4,P2-S3) 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.

The differences of the four models declared this time are shown in the table below :

Model	P2-K4	P2-K3	P2-S4	P2-S3
Appearance	 P2-K4 and P2-K3 have the same appearance.		 P2-S4 and P2-S3 have the same appearance.	
Gear setting	Select 1-4 gears	Select 1-3 gears	Select 1-4 gears	Select 1-3 gears
Max flow	0.84 L/min	0.63 L/min	0.84 L/min	0.63 L/min
Battery model	BA-K201/BA-K200/BA-K202		BA-K201/BA-S200/BA-S202	

VI. Principle of operation

Both model (Model:P2-K4,P2-K3,P2-S4,P2-S3) 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

Indications for Use:The Portable Oxygen Concentrator (Model:P2-K4,P2-K3,P2-S4,P2-S3) is intended to provide supplemental oxygen in a home, institutional, or travel environment.

It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Portable Oxygen Concentrator(Model: P2-K4,P2-K3,P2-S4,P2-S3) is small, portable and may be used in home, institution and various mobile environments. However, there is not any type of humidifier that is suitable for use with this device because of its pulse dose delivery mode.

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	**Same**
4	**Model**	P2-K4,P2-K3,P2-S4,P2-S3	P2-E6	**Same**
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-K4,P2-K3,P2-S4,P2-S3) 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**	ISO 10993- 5 tested for Cytotoxicity; ISO 10993-10 tested for Skin Sensitization; ISO 10993-23 tested for Skin	ISO 10993- 5 tested for Cytotoxicity; ISO 10993-10 tested for Sensitization	**Same**

	performed	Irritation; ISO 18562-2 tested for Particulate matter; ISO 18562-3 tested for Volatile organic Compounds;	and Irritation; ISO 18562-2 tested for Particulate matter; ISO 18562-3 tested for Volatile organic Compounds;	
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**	P2-S4/P2-S3:6.69"H*3.39"W*6.18"L P2-K4/P2-K3:6.69"H*3.39"W*5.51"L	6.30"H*3.35"W*8.70"L	**Subject device is smaller and more portable**
20	**Weight**	3.31lbs±0.07lbs (with BA-K201 battery)	4.34lbs±0.07Ibs (with standard battery)	**Subject device weighs less than Predicate device**
21	**Oxygen Concentration**	90%-3%/+6% at all settings	90%-3%/+6% at all settings	**Same**
22	**Setting**	P2-S4/P2-K4：adjustable in 1increments from 1 to 4. P2-S3/P2-K3：adjustable in 1increments from 1 to 3.	Adjustable in 1 increments from 1 to 6	**Different (See below note ID_22)**
23	**Pulse mode bolus size**	P2-S4/P2-K4：42 mL per breath at setting 4 with 20 BPM P2-S3/P2-K3：31.5 mL per breath at setting 3 with 20 BPM	60 mL per breath at setting 6 with 20BPM	**Different (See below note ID_23)**
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 DC adaptor: 12 - 16V DC in,19V 6A out	AC adaptor: 100-240VAC ;50-60 Hz In,19VDC 5.26A out DC adaptor: 12 - 16V DC in,19V 6A out	**Same**
29	**Maximum oxygen discharge pressure**	P2-S4/P2-K4: 16.0 PSI (110KPa)	18.3 PSI (126KPa)	**Different (See below note ID_29)**
		P2-S3/P2-K3: 14.1 PSI (97KPa)		
30	**Inspiratory trigger sensitivity**	-0.12cm/H20	-0.12cm/H20	**Same**
31	**Software**	Embedded	Embedded	**Same**
32	**Acoustic Noise**	P2-S4: 55.3dBA at 0.84 LPM	58.2 dBA at 1.2 LPM	**Different (See below note ID_32)**
		P2-S3: 55.8dBA at 0.63 LPM		
		P2-K4: 55.3dBA at 0.84 LPM		
		P2-K3: 55.1dBA at 0.63 LPM		
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	
45		Alarms	Alarms	
46	**Battery Duration**	BA-K201:Up to 2.5 hours at 0.21 LPM BA-K200/BA-S200:Up to 4.8 hours at 0.21 LPM BA-K202/BA-S202:Up to 7.2 hours at 0.21 LPM	Up to 4.5 hours at 0.21 LPM	**Different (See below note ID_46)**
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	**Same**

			meters)	
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**	VOC's less than ambient	VOC's less than ambient	**Same**
52	**Standards Met**	ANSI AAMI ES 60601- 1: 2005 /A1:2012 and A2:2020 IEC 60601-1-2: 2014 IEC 60601-1-11: 2015/A1:2020 IEC 60601-1-8: 2006/ A1:2012 /A2:2020 IEC 60601-1-6: 2010/ A1:2013 /A2:2020 ISO 80601-2-69: 2020 ISO 80601-2-67: 2020 ISO 18562-2: 2017 ISO 18562-3: 2017 IEC 62133: 2017 ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-23:2021	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	**The main equipment conforms to the latest standards**

Note:

ID_22: The max setting of subject device P2-E6 is 6 and of subject device

P2-S4/P2-K4 is 4(P2-K4,P2-S4 has a different appearance),P2-S3/P2-K3 is 3(P2-K4,P2-S4 has a different appearance).Those risks are mitigated by tests tested according to ISO 80601-2-69: 2020, ISO 80601-2-67: 2020 ,ISO 18562-2: 2017, ISO 18562-3: 2017,ISO 10993-5:2009,ISO10993-10:2021 and ISO10993-23:2021 therefore the difference does not raise new questions of safety and effectiveness.

ID_23：The pulse modebolus size subject device P2-S4/P2-K4/P2-S3/P2-K3 is smaller than predicate device P2-E6 (K210371).P2-S4/P2-K4(P2-K4,P2-S4 has a different appearance) maximum gear is 4, and the maximum flow rate is 0.84 LPM.P2-S3/P2-K3(P2-K3,P2-S3 has a different appearance) maximum gear is 3,and the maximum flow rate is 0.63 LPM.Those risks are mitigated by tests tested according to ISO 80601-2-67: 2020 therefore the difference does not raise new questions of safety and effectiveness.

ID_29：The Maximum oxygen discharge pressure of subject device P2-S4/P2-K4 and P2-S3/P2-K3 is different with predicate device P2-E6 (K210371).Since the subject device has been tested against ISO 80601-2-69: 2020 with positive result,the difference of subject device do not raise new questions of safety and effectiveness.

ID_32：The Acoustic Noise of subject device P2-S4/P2-K4/P2-S3/P2-K3 is litter smaller than predicate device P2-E6 (K210371).Since the subject device has been tested against ISO 80601-2-69: 2020 and ANSI AAMI ES 60601- 1: 2005 /A1:2012 and A2:2020 with positive result,the difference of subject device do not raise new questions of safety and effectiveness.

ID_46：The subject device P2-S4/P2-K4/P2-S3/P2-K3 can be equipped with three different types of battery, BA-K201 for P2-S4/P2-K4/P2-S3/P2-K3, BA-K200, BA-K202 for P2-K4/P2-K3. BA-S200,BA-S202 for P2-S/P2-S3.Those risks are mitigated by tests tested according to IEC 62133: 2017 therefore the difference does not raise new questions of safety and effectiveness.

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

The device has been tested and verified in various phases, internal testing, verification and validation as well as external testing and validation. The design was verified throughout the design process. Risk analysis was done, appropriate measures were implemented and their effectiveness verified.The standard for external test execution are shown in the following table:

Standards	Standards Name
ANSI AAMI ES 60601- 1: 2005 /A1:2012 and A2:2020	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/A1:2020	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
IEC 60601-1-8: 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 60601-1-6: 2010/ A1:2013 /A2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 80601-2-69: 2020	Medical electrical equipment. Particular requirements for the basic safety and essential performance of oxygen concentrator equipment
ISO 80601-2-67: 2020	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: 2017	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-Part2: Lithium systems
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 on the subject device.P2-K4,P2-K3,P2-S4,P2-S3. The system complies with the AAMI ANSI

ES60601-1, IEC 60601-1, IEC 60601-1-8, IEC 60601-1-6, 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.

●Biological compatibility Testing

Biological compatibility testing were conducted on the subject device(P2-S4),The device complies with the ISO 10993-5,ISO 10993-10, ISO 10993-23,ISO 18562-2, ISO 18562-3 standards.

●Battery Testing

The battery equipped with the device is tested according to the IEC62133 standard. The battery meets the IEC622133 standard.

●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.

The test platform ensures compliance to recognized consensus standards and therefore does not raise new questions of safety and effectiveness.

X. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

XI. Conclusions

The Portable Oxygen Concentrator (Model: P2-K4,P2-K3,P2-S4,P2-S3) 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-K4,P2-K3,P2-S4,P2-S3) 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-K4,P2-K3,P2-S4,P2-S3) performs as intended in the specified use conditions are same with predicate device. The performance tests demonstrate that the Portable Oxygen Concentrator (Model: P2-K4,P2-K3,P2-S4,P2-S3) performs comparably to the predicate device that is currently marketed for the same intended use. Thus,

Portable Oxygen Concentrator (Model: P2-K4,P2-K3,P2-S4,P2-S3) is Substantially Equivalent (SE) to the predicate device.