February 28, 2025

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

Re: K242718
Trade/Device Name: Portable Oxygen Concentrator (P2-TOC)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: January 27, 2025
Received: January 27, 2025

Dear Benrong Zhang:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242718

Device Name
Portable Oxygen Concentrator (P2-TOC)

Indications for Use *(Describe)*
The Portable Oxygen Concentrator P2-TOC 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.

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: 20/01/2025

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	K240354
Common Name	Generator, Oxygen, Portable
Classification name	Portable oxygen generator
Trade Name	Portable Oxygen Concentrator (Model:P2-TOC)
Review panel	Anesthesiology
Product code	CAW
Regulation Number	868.5440
Regulation Class	2

IV. Predicate Device Information

1	**Product name**	Portable Oxygen Concentrator. Model: P2-S4,P2-S3,P2-K4,P2-K3
	510(k) number	K230702
2	**Product name**	Portable Oxygen Concentrator. Model: P2-E7,P2-E

	510(k) number	K223379
3	**Product name**	Portable Oxygen Concentrator. Model: P2-E6
	510(k) number	K210371
4	**Product name**	Kingon P2 Oxygen Concentrator
	510(k) number	K190304

V. Device description and Indications for Use

Device description: The Portable Oxygen Concentrator P2-TOC is a device that uses the principle of molecular sieve pressure swing adsorption to increase oxygen concentration by adsorption of nitrogen and other gas components. The device needs to be used with a nasal oxygen cannula, which can provide oxygen supplementation to the user.

The Portable Oxygen Concentrator P2-TOC has two oxygen supply modes, namely continuous oxygen supply mode and pulse oxygen supply mode. Hereinafter referred to as "continuous mode" and "pulse mode" .

In the continuous mode, the Portable Oxygen Concentrator P2-TOC can continuously deliver oxygen at a fixed flow rate. In the pulse mode, the Portable Oxygen Concentrator P2-TOC is able to deliver oxygen only when the user inhales by detecting the human respiratory rate.

Indications for Use: The Portable Oxygen Concentrator P2-TOC 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 adult only.

VI. Principle of operation

The Portable Oxygen Concentrator P2-TOC 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 in the Air receiver. 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. Comparison with predicate device

Model 1000 Portable Oxygen Concentrator and Model 4000 that manufactured by CAIRE was selected for comparison. See the following table for details of comparison:

ID	Items	Predicate Device (K013931)	Reference Device (K120785)	Device to be submitted for 501K	Comparison
1	**Device Name**	Omni Portable Oxygen Concentrator	eQuinox Oxygen System	Portable Oxygen Concentrator	Similar
2	**Model**	Model 1000	Model 4000	P2-TOC	Different model names
3	**Indication for Use**	The Omni portable oxygen concentrator is intended for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities.	The eQuinox is intended for the administration of supplemental oxygen. The device is not intended for life support, nor does it provide any patient monitoring capabilities.	The Portable Oxygen Concentrator P2-TOC is intended to provide supplemental low flow oxygen.. The device is not intended for life support, nor does it provide any patient monitoring capabilities.	Similar (See below note ID_3)
4	**Environment of Use**	Home, outside the home and institutions	Home, outside the home	Home, outside the home	Similar (See below note ID_4)
5	**Prescriptive**	Yes	Yes	Yes	Same
6	**Patient Interface**	Nasal Cannula	Nasal Cannula	Nasal Cannula	Same
7	**Technology**	Pressure Swing Adsorption with molecular sieve	Pressure Swing Adsorption with molecular sieve	Pressure Swing Adsorption with molecular sieve	Same
8	**Dimensions**	19.3 high x 12.3 wide x 7.1 deep (inches) 49.0 height x 31.2 wide x 18.0 deep	15.5 high x10.8 wide x 7.3 deep (inches)	11.1 length x 6.7 width x15 height (inch) 28.2 length x 17.1 width x 38.2 height (cm)	Different (See below note ID_8)

		(cm)			
9	**Weight**	17.9 pounds (8.1 kg) with Power Cartridge	12lbs	18.8 lbs / 8.5kg (with battery)	Different (See below note ID_9)
10	**Oxygen Concentration**	90% +/– 3% for all flow settings	90%+3%/-3% at all settings	90%-3%/+6% at all settings	Different (See below note ID_10)
11	**Equivalent Flow Rates**	Continuous Flow Mode: 1.0-3.0 LPM	Continuous Flow Mode: 1.0-3.0 LPM	Continuous Flow Mode: 1.0-3.0 LPM	Different (See below note ID_11)
		Pulse Dose Mode: 16-96 ml Pulse Volumes 6 to 25 breaths per minute average, sustainable	Pulse Dose Mode: 16-192 ml Pulse Volumes Breathing rate is 15 times a minute	Pulse Dose Mode: 5-133 ml Pulse Volumes Breathing rate is 15 times a minute Pulse Dose Mode: 5-200 ml Pulse Volumes Breathing rate is 10 times a minute	
12	**Filters**	Air Inlet Filter	Air Inlet Filter	Air Inlet Filter	Same
13	**User Interface**	Buttons, LCD Display	Buttons, LCD Display	Buttons, LCD Display	Same
14	**Power Supply**	AC Power (100-240 VAC, 50-60 Hz) DC Power (12V nominal) Battery (Lithium Ion)	AC Power (100VAC, 50-60 Hz) DC Power (12V nominal) Battery (Lithium Ion)	AC Adaptor (Input: 100-240 VAC, 50-60 Hz) DC Adaptor (Input: 11-16 VDC Output: 19V) Battery (Lithium Ion)	Similar (See below note ID_14)
15	**Software**	Embedded	Embedded	Embedded	Same
16	**Acoustic Noise**	48 dBA at 3.0 LPM in Continuous Flow Mode 40 dBA at 3.0 LPM in Pulse Flow Mode	≤40 dBA	≤ 60dB (A) (Gear 10 of pulse mode/ Gear 5 of continuous mode)	Different (See below note ID_16)
17	**Alarms**	Loss of power	Loss of power	Loss of power	Different (See below note ID_17)
		Low Battery	Low Battery	Low Battery	
		Low Therapeutic O_2 Output	Low Therapeutic O_2 Output	Low O_2 Concentration	
		O2 flow outside normal limits	O2 flow outside normal limits	Gas Delivery Fail	

		No Inspiration detected in Pulse Dose Mode	No Inspiration detected in Pulse Dose Mode	Absenceof Breath (Only in Pulse Mode)	
		Unit Malfunction	Unit Malfunction	System Startup Fail	
18	**Status Indicator**	Tool icon	Tool icon	Tool icon	Same
		Battery Status Gauge	Battery Status Gauge	Battery Status Gauge	Same
		External Power Indicator	External Power Indicator	External Power Indicator	Same
		Flow Control Setting	Flow Control Setting	Flow Control Setting	Same
		Low Priority Technical Alarm	Low Priority Technical Alarm	Low Priority Technical Alarm	Same
		Buzzer	Buzzer	Buzzer	Same
19	**Battery Duration**	Up to 5.4 hours (Pulse setting of 1.0 at 12 BPM)	Up to 5.94 hours (Pulse setting of 1.0 at 12 BPM)	Up to 7.0 hours（Pulse setting of gear 1 at 20 BPM）	Different (See below note ID_19)
20	**Operating Environment**	Temperature: 50º F to 104º F (10º C to 40º C) Relative humidity: 10% - 95% at an 82.4° F (28°C) dew point Altitude: 0 – 13,123 feet (0 - 4,000 meters)	0 ºC tot 40 ºC (32 ºF tot 104 ºF)	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, 70kPa to 106kPa)	Different (See below note ID_20)
21	**Shipping Storage Environment**	-4º F to 140º F (-20º C to 60º C) Relative humidity: Up to 95% Non-Condensing	-25 °C tot 70 °C (-13 °F tot 158 °F) Vochtigheid: tot 95% niet condenserend -20 °C tot 50 °C (-4 °F tot 122 °F) voor accu's	Temperature: -4 to 158˚F (-20 to 70˚C) Humidity: 5% to 90%, non-condensing Store in a dry environment Altitude range: 0 to 10,000 ft (0 to 3048 meters,70kPa to 106 kPa)	Different (See below note ID_21)
22	**Principle of Operation**	Pulse Flow Mode is designed to deliver 16 ml boluses of oxygen per incremental	Pulse Flow Mode is designed to deliver 16 ml boluses of oxygen per incremental flow	The Portable Oxygen Concentrator P2-TOC works by getting use of the molecular sieves	Similar. Both use pressure

		flow setting for each patient inspiration detected.Bolus volume is held constant regardless of breath rate within a given setting. Delivery of the bolus is triggered by detection of the end of inspiration followed by the start of a subsequent inspiration. Sensitivity is dealer/provider adjustable. Based on this inspiration trigger signal, a “pulse” of oxygen is released to the patient by an electronically controlled flow valve. There is no mixing of oxygen with room air.	setting for each patient inspiration detected.Bolus volume is held constant regardless of breath rate within a given setting. Delivery of the bolus is triggered by detection of the end of inspiration followed by the start of a subsequent inspiration. Sensitivity is dealer/provider adjustable. Based on this inspiration trigger signal, a “pulse” of oxygen is released to the patient by an electronically controlled flow valve. There is no mixing of oxygen with room air.	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.	swing adsorption with molecular sieve.
23	**Device Components**	Oxygen concentrator, Universal Cart, AC Power Supply, DC Power Supply, Battery.	Oxygen concentrator, Cart, AC Power Supply DC Power Supply, Battery.	Oxygen concentrator, Cart, AC Power Supply, AC Power Supply, Battery, Backpack.	Similar.A backpack is provided for patient convenience
24	**Materials for filters**	Chemical fiber	Chemical fiber	Chemical fiber	Same
25	**Material of Patient contact components**	Button panel: PET Main housing: PC+ABS	Button panel: PET Main housing: PC+ABS	Button panel: PET Main housing: PC+ABS	Same
26	**Patient**	Adult	Adult	Adult	Same

	Population				
27	**Single Patient, multi-use**	Yes	Yes	Yes	Same
28	**Electrical Safety Classification**	Class II	Class II	Class II	Same
29	**Electrical Safety**	IEC 60601-1	IEC 60601-1	IEC 60601-1	Same
30	**Electromagnetic compatibility**	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	Same
31	**Biocompatibility**	PM2.5,PM10, VOC's less than ambient	PM2.5,PM10, VOC's less than ambient	PM2.5,PM10, VOC's less than ambient	Same
32	**Output pressure**	5.0 psi nominal	5.0 psi nominal	5 PSI	Same
33	**Classification**	21CFR 868.5440	21CFR 868.5440	21CFR 868.5440	Same
34	**Product Code**	CAW	CAW	CAW	Same
35	**FDA Class**	II	II	II	Same
36	**Heat ex-changer**	Cooling fan	Cooling fan	Cooling fan	Same

Note:

ID3,ID4:

The Indication for Use description of P2-TOC is similar to the description of Model 1000 and Model 4000. We added a "low flow" reference to the intended use to prevent user misunderstanding and reduce risk.

The Environment of Use of P2-TOC is basically the same as the description of Model 1000 and Model 4000.Therefore the difference does not raise new questions of safety and effectiveness.

ID8:

The dimensions of Model 1000and Model 4000 compared and theP2-TOC devices differ in dimensions due to their different designs.The risk is mitigated by tests tested according to ISO 80601-2-69: 2020,IEC60601-1and ISO 80601-2-67: 2020, therefore the difference does not raise new questions of safety and effectiveness.

ID9, ID14, ID20 and ID21:

Although the weight, power supply, operating and shipping storage environment conditions of P2-TOC is different from the predicate devices (Model 1000 and Model 4000), but the subject device has passed the IEC60601-1 test. Hence, the differences don't raise new questions of safety and effectiveness.

ID10:

The oxygen concentration of predicate devices Model1000 and Model 4000 both are 90% +/– 3% for all flow settings and of subject device P2-TOC is 90%-3%/+6% at all settings. The risk is mitigated by tests tested according to ISO 80601-2-69: 2020 and ISO 80601-2-67: 2020, therefore the difference does not raise new questions of safety and effectiveness.

ID11:

In continuous mode, both P2-TOC and predicate devices (Model 1000 and Model 4000) have same ranges of 1.0-3.0L/min.

In pulse mode, the flow range of the Model1000 is 16-96 mL. The breathing rate is 6-25 beats per minute, so the maximum flow rate in pulse mode is 2400ml (25*96mL).

In pulse mode, the flow range of the Model4000 is 16-192mL when the breathing rate is 15 times per minute, so the maximum flow rate in pulse mode is 2880mL (15*192mL).

In pulse mode, the maximum flow rate of P2-TOC is 2000mL. The flow rate is smaller than that predicate devices. (Model 1000 and Model 4000).

The risk is 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.

ID16:

The acoustic noise of subject device P2-TOC is litter bigger than predicate device Model 1000. Since the subject device has been tested against ISO 80601-2-69: 2020 and IEC60601- 1: 2005 /A1:2012 and A2:2020, the standard requirements have been met.The difference of subject device do not raise new questions of safety and effectiveness.

ID17:

The subject device and the predicate device have differences in alarms information displayed. However, the subject device meets the requirements of the standard ISO80601-2-69 and IEC60601-1-8. In addition, performance testing, risk analysis has been conducted on the

subject device. Hence, the difference of subject device do not raise new questions of safety and effectiveness.

ID19:

The subject device P2-TOC can be equipped with the battery, which can up to 9.0 hours (in pulse setting of 1 at 20 BPM). The risk is mitigated by test tested according to IEC 62133: 2017, therefore the difference does not raise new questions of safety and effectiveness.

VIII. 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 and ISO 80601-2-67 for performance and IEC 62304 for software verification are complied. See below table for details:

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: 2020	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
IEC 60601-1-11: 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 18562-1: 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
IEC 62133-2: 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 10993-1:2018	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 on the subject device model P2-TOC. 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.

•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 on the subject device model P2-TOC. 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 Portable Oxygen Concentrator (Model: P2-TOC) have the same intended use and similar characteristics as the cleared predicate device Portable Oxygen Concentrator, model 1000 and model 4000. Moreover, bench testing contained in this submission supplied demonstrate that the differences existed between Portable Oxygen

Concentrator (Model: P2-TOC) and Portable Oxygen Concentrator, model 1000 and model 4000 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-TOC) performs as intended in the specified use conditions are same with predicate device. The performance tests demonstrate that the Portable Oxygen Concentrator (Model: P2-TOC) performs comparably to the predicate device that is currently marketed for the same intended use. Thus, Portable Oxygen Concentrator (Model: P2-TOC) is Substantially Equivalent (SE) to the predicate device.