February 29, 2020

Qingdao Kingon Medical Science and Technology Co.
% Roman Huang
General Manager
Elliot Medical Solutions
Parkland Drive
Cleveland Heights, Ohio 44106

Re: K190304
Trade/Device Name: Kingon Portable Oxygen Concentrator P2
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: January 15, 2020
Received: January 24, 2020

Dear Roman Huang:

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 ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190304

Device Name

Kingon Portable Oxygen Concentrator P2

Indications for Use *(Describe)*

The Kingon P2 is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable, and is capable of continuous use in the home, institutional, and travel / mobile environments.

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.

Section 4

510(k) Summary

1. **Company making the submission:**
   Company Name – Qingdao Kingon Medical Science and Technology Co., Ltd
   Company Address - 24th East Building, No. 252 Yanhe Road, Tianhe Industrial Park, Huangdao, Qingdao, Shangdong, China
   Tel: 86-0532-58792324
   Contact – Wu Xiao
   CEO and Chief Manager

2. **U.S. Correspondent and Contact**
   Name: Elliot Medical Solutions
   Address: Cleveland Heights, Cleveland, Ohio
   Contact: Roman Huang
   General Manager
   Tel: 216-262-0962
   Email: support@elliotmd.com

3. **Submitted device**
   Device Name: Portable Oxygen Concentrator
   Trade name: Kingon Portable Oxygen Concentrator
   Models: P2
   Common Name: Oxygen Concentrator
   Classification Name: Oxygen Concentrator, Portable
   Regulation Number: 868.5440
   Regulatory Class: II
   Product Code: CAW
   Type of 510(k) submission: Traditional

4. **Last Edited Date**
   February 28, 2020

5. **Predicate Device.**

Manufacturer	Predicate Device	510(k) number
Philips Respironics SimplyGo Oxygen Concentrator	SimplyGo Portable Oxygen Generator	K111885

6. Description.

The Kingon P2 oxygen concentrator includes the following items:

- One Kingon P2 oxygen concentrator
- One Carry bag
- One Nasal cannula
- One AC power supply
- Five Intake filters
- One Battery
- One User manual

The Kingon P2 oxygen concentrator utilizes a molecular sieve and differential pressure swing adsorption to separate the gases in ambient air. In brief, after the device takes the room air, the molecular sieve packed in a sealed container can absorb nitrogen in the air, and the oxygen still exists in gaseous form that can be collected by specially designed pipelines and deliver to patients. When the environmental air pressure decreases, exhaust of the vacuum container occurs and nitrogen will be released from the molecular sieve. When the patient inhales, the device senses the pressure change and is triggered to release the oxygen pulse. In between breaths, the device regenerates an oxygen pulse and waits for the next inhalation breath before dispensing it. In this way, Kingon P2 device can concentrate the oxygen in the air to produce a pulse of oxygen between 87-96% in purity.

7. Indication for use.

The Kingon P2 is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable, and is capable of continuous use in the home, institutional, and travel / mobile environments.

8. Similarities/Differences between the subject and predicate device.

Element of Comparison	Predicate Device	Subject Device	Comparison
Device name	Philips Respironics SimplyGo Portable Oxygen Concentrator	Kingon P2 Portable Oxygen Concentrator	
510(k)	K111885	N/A	
Indication for Use	The Portable Oxygen Concentrator is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable and is capable of continuous use in the home,	Same	Identical

	institutional, and travel/mobile environments.		
Environment of Use	Home, institutional, and travel/mobile environments.	Same	Identical
Patient Population	Adult	Same	Identical
Single Patient, multi-use	Yes	Yes	Identical
Patient Interface	Standard Single Lumen Nasal Cannula	same	Identical
Technology	Pressure Swing Adsorption with molecular sieve	same	Identical
Dimensions	3.6''H*8.3"w*9.4(Standard Battery) 3.6"H*8.3"W*10.27"L(Extend Battery)	6.30"H*3.35"W*8.70"L	Similar
Weight	5.0 lbs (with standard battery installed) 6.0 lbs (with extended battery installed)	4.34lbs (±0.07Ibs with standard battery)	Similar
Oxygen Concentration	At least 87% at all settings (maximum of 96%) over the rated environmental range.	Same	Similar
Equivalent Flow rates	15-40 BMP increments of 5BPM.	10-40BMP increments of 5BPM.	Similar
Dose at Specified Flow	11mL per setting	10.5mL per setting (with 20BPM)	Identical
Filters	Input Filter; Patient Filter	same	Identical
User Interface	Buttons LCD Display	same	Identical
Electrical	100-240 VAC; 50/60 Hz 19 VDC, 6.3 A	100-240VAC ;50-60 Hz; 19 VDC + 5% 6A MAX	Similar
Acoustic Noise	42 dBA typical at setting 2 and 20 BPM 48 dBA typical at setting 5 and 20 BPM (when measured at 1 meter from front of the device)	49 dBA typical at setting 2 and 20BPM 56 dBA typical at setting 5 and 20 BPM (when measured at 1 meter from front of device)	Similar
Alarms	High Breath Rate Alarm	same	Similar
	Low Oxygen Concentration Alarm	same	
	Technical Fault Alarm	same	
	Low Battery Alarm	same	

	Warm Up Indicator	same	
	No Flow Alarm	same	
	External Power Failure Alarm	same	
	Depleted Battery Alarm	same	
Status Indicator	Tool icon	same	Similar
	Flow Setting	same	
	Battery Charge Level	same	
	Alarm Silence Symbol	same	
	Attention	same	
	Flow Control Setting	same	
Battery Duration	Up to 4.5 hours (Pulse setting of 2 at 20 BPM with Standard battery) Up to 9 hours (Pulse setting of 2 at 20 BPM with Extended battery)	Up to 3.8 hours（Pulse setting of 1 at 20 BPM with Standard battery）	Similar
Operating Environment	Temperature: 41° F to 95° F (5° C to 35° C) Relative humidity: 15% to 93% Atmospheric Pressure: 700 hPa to 1010 hPa Altitude: up to 10,000 ft (3048 m)	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)	Similar
Shipping Storage	-4° F to 140° F (-20° C to 60° C) Relative humidity: up to 93%, non-condensing	Temperature: -4 to 158˚F (-20 to 70˚C) Humidity: 5% to 90%, non-condensing Store in a dry environment	Similar

9. Comparison of Technological Characteristics with Predicate Device.

Both the Kingon P2 oxygen concentrator and the predicate device (SimplyGo) have the same indication of use. Both of them have incorporated the same basic design and the same technological characteristics, and utilize the same operating principle. Both of them have been tested to the same electrical and electromagnetic safety standards for medical electrical equipment. And both of them are manufactured under a quality system. The differences between the subject device and predicate such as size, storage condition, operating condition, battery duration, alarm setting and panel indicator introduce risks mitigated by the performance testing provided in this submission.

10. Safety and Performance Data, Biocompatibility Data

Safety and performance data of the Kingon P2 device are listed in Table as below.

Bench Tests	Standards	Results	Report File No.
General requirements for basic safety and essential performance	IEC 60601-1	Pass	GZME18010 0001801
General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	IEC 60601-1-11	Pass	GZME18010 0001802
Medical electrical equipment part 2: particular requirements for the basic safety and essential performance of oxygen concentrator equipment	ISO 80601-2-69	Pass	GZME18010 0001803
ISO 80601-2-67: medical electrical equipment, part 2-67: particular requirements for basic safety and essential performance of oxygen-conserving equipment	ISO 80601-2-67	Pass	GZME18010 0001804
IEC 60601-1-8: Medical electrical equipment, 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 system	IEC 60601-1-8	Pass	GZME18010 0001805
EMC TEST	IEC 60601-1-2	Pass	GZME18010 0001901
Radiated & Conducted emissions test (FCC)	47 CFR Part 15, subpart B	Pass	GZME18010 0001902
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	IEC 62133, ST/SG/AC.10/11/ Rev.6/Section 38.3	Pass	SHES180500 540701
Electromagnetic Immunity from RFID reader	AIM standard 7351731	Pass	1909ESU013 -U1

Biocompatibility data are listed in Table as below:

Biocompatibility Tests	Standards	Results	Report File name and Number
In vitro cytotoxicity test of shell and accessories	ISO 10993-5:2009 Test Method MTT Method MEM with 10% FBS extract	Pass	SDWH-M201800623-1
Skin sensitization test of shell and accessories	ISO 10993-10: 2010 Test Methods Guinea Pig Maximization Test 0.9% Sodium Chloride Injection Extract	Pass	SDWH-M201800623-2
Skin sensitization test of shell and accessories	ISO 10993-10: 2010 Test Methods Guinea Pig Maximization Test Sesame oil extract	Pass	SDWH-M201800623-3
Skin irritation test of shell and accessories	ISO 10993-10: 2010 Test Methods 0.9% Sodium Chloride Injection Extract	Pass	SDWH-M201800623-4
Skin irritation test of shell and accessories	ISO 10993-10: 2010 Test Methods Sesame oil extract	Pass	SDWH-M201800623-5

Tests	Standards	Results	Report File name and Number
Emission of VOCs and aldehydes	ISO 18562-3	Pass	18914-N01
Emissions of particulate matter, carbon dioxide, carbon monoxide and ozone	ISO 18562-2	Pass	18914-N02
Biological evaluation of medical devices – part 17: establishment of allowable limits	ISO 10993-17 ISO 18562-1	Pass	18914-N03

for leachable substances			

10. Conclusion.

The Kingon P2 oxygen concentrator has similar intended use, principle of operation, and similar technological characteristics as the predicate device identified. Performance testing contained in this submission demonstrates the minor differences in technological characteristics between the subject device and the predicate do not raise different questions of safety and effectiveness. Thus, in accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part807 and based on the information provided in this premarket notification, we conclude that Kingon P2 oxygen concentrator is substantially equivalent to predicate device.

End.