DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 24, 2017

Oxus, Incorporated
Ryan Lenarcic
Quality & Regulatory Manager
2676 Paldan
Auburn Hills, Michigan 48326

Re: K162433
Trade/Device Name: GCE Zen-O Portable Oxygen Concentrator Model RS-00500
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: April 19, 2017
Received: April 24, 2017

Dear Ryan Lenarcic:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Lori A. Wiggins -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162433

Device Name
GCE Zen-O™ Portable Oxygen Concentrator
Model RS-00500

Indications for Use *(Describe)*
The Portable Oxygen Concentrator 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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Section V 510(k) Summary (As required by section 807.92(c))

I. Submitter

Oxus Inc.
2676 Paldan Dr.
Auburn Hills, MI 48326

Phone: 248-475-0925
Fax: 248-475-0938

Contact Person: Ryan Lenarcic, Quality & Regulatory Manager
Date Prepared: February 22, 2017

II. Device

Name of Device:	GCE Zen-O™ Portable Oxygen Concentrator Model RS-00500
Common or Usual Name:	Portable Oxygen Concentrator
Classification Name:	Portable oxygen generator (21 CFR 868.5440)
Regulatory Class:	II
Product Code:	CAW

III. Predicate Device:

Oxus, RS-00400 Portable Oxygen Concentrator, K073242
This Predicate has not been subject to a design related recall

No reference devices were used in this submission

IV. Device Description

Oxus, Inc. as indicated above proposes to offer the following device which we will refer to as the GCE Zen-O™ Portable Oxygen Concentrator, Model RS-00500.

The GCE Zen-O™ (Model RS-00500) POC is the latest design of POC from Oxus, Inc. The previous model, Oxus Model RS-00400, is FDA cleared under 510(k) K073242. During the

launch of the RS-00500 model in 2015, submission of a new 510(k) was not required per FDA Guidance document “Deciding When to Submit a 510(k) for a Change to an Existing Device” and a subsequent Letter to File was generated. Due to recent business partnerships that have led to the sale of the RS-00500 design from Oxus to GCE, Oxus is submitting this 510(k) to procure a stand-alone 510(k) clearance for the GCE Zen-O POC™ (Model RS-00500) separate from the Oxus RS-00400 model. Information provided within this submission references both model numbers due to the sharing of technology and previous testing; however this submission is solely for the clearance of the GCE Zen-O™ POC, Model RS-00500
The GCE Zen-O™ POC delivers 87% - 96% oxygen to a patient through a standard single-lumen nasal cannula. The GCE Zen-O™ POC detects a patient breath and operates by delivering a bolus of oxygen during the inhalation period (pulse mode) or can provide a continuous flow of oxygen (continuous mode).

The device is portable, enabling patients who need an oxygen device to be treated at home according to a clinician’s prescription or direction.

The GCE Zen-O™ POC can be set to deliver flowrates between 1-6 LPM in pulse mode and 0.5-2 LPM in continuous mode; both with increments of 0.5 LPM to a patient. The device can be operated when powered by the 100-240VAC AC/DC power supply provided with the unit and designed to operate with a DC automotive adaptor. In addition, the device contains a rechargeable battery allowing it to be carried by a patient while traveling

V. Indications for Use

The Portable Oxygen Concentrator is intended to provide supplemental oxygen in a home, institutional, or travel environment.

Patient Population:

Adult patients with chronic pulmonary diseases such as chronic bronchitis, emphysema, asthma, or lung cancer, those in the terminal stage of cancer, or any patient requiring supplemental oxygen.

The GCE Zen-O™ POC is not intended for use in life supporting or life sustaining situations, and is provided non-sterile. It is a prescription only device, and designed for indoor and outdoor use.

Environment of Use:

Travel, Home or Institution

VI. Comparison of Technological Characteristics with the Predicate Device

Pressure Swing Absorption (PSA) is the technological principle for both the subject and predicate devices. It is based on molecular sieve / pressure swing absorption technology, which draws ambient air, pushes it through a sieve bed, then utilizes pressure swing absorption to convert the ambient air to pure oxygen.

Table 1 compares the key features of the proposed GCE Zen-O™ POC with the identified predicate. The comparison demonstrates that the device can be found to be substantially equivalent to the identified predicate.

Table 1 – Comparison of Proposed Device vs. Predicate

Attribute	Predicate Device: K073242 RS-00400	Proposed Device: GCE Zen-O™ RS-00500
Indications for Use	The Oxus RS-00400 Portable Oxygen Concentrator is intended to provide supplemental oxygen in a home, institutional, or travel environment.	The GCE Zen-O™ Portable Oxygen Concentrator is intended to provide supplemental oxygen in a home, institutional, or travel environment.
Environments of Use	Travel, Home or Institution	Travel, Home or Institution
Prescriptive	Yes	Yes
Patient Population	Adult	Adult
Single Patient, multi-use	Yes	Yes
Patient Interface	Cannula port	Cannula port
Technology	Pressure Swing Adsorption with molecular sieve	Pressure Swing Adsorption with molecular sieve
Dimensions	4.6” H x 7.5” W x 11.6” L	6.6” H x 8.3” W x 12.3” L
Weight	10 lbs	10.25 lbs
Oxygen Concentration	87% - 96%	87% - 96%
Equivalent Flow Rates	1-5 LPM, increments of 0.5 LPM	1-6 LPM, increments of 0.5 LPM 0.5 – 2 LPM, increments of 0.5 L (Continuous mode)

Attribute	Predicate Device: K073242 RS-00400	Proposed Device: GCE Zen-O™ RS-00500
Dose at Specified Flow	8.5 mL per setting	11 mL per setting
Filters	Input Filter Intermediate Filter Patient Filter	Input Filter Patient Filter
User Interface	Buttons LCD Display	Buttons LCD Display
Electrical	100-240VAC, 50/60 Hz, 1.6A 18VDC, 7A	100-240VAC, 50/60 Hz, 2.5A 24VDC, 6.25A
Software	Embedded	Embedded
Acoustic Noise	42 dBA at 2 LPM	42 dBA at 2 LPM
Alarms	• Battery empty • Low Pressure • No pulse • High temp • RAM failure • Motor stall • Compressor failure • Fan failure • Low Battery • No Breath Detected • MP timeout • EEPROM failure • EEPROM error • Replace filter • Clean input filter • Low RTC battery	• Battery empty • Low Pressure • Motor communication • No pulse • Skipped Breaths • High temp • RAM failure • Motor stall • Compressor failure • Fan failure • Invalid Battery • Low Flow • Low Battery • No Breath Detected • uC timeput • EEPROM failure • EEPROM error
Status Indicators	Flowrates Battery Condition Alarms History Log Diagnostics	Flowrates Battery Condition Alarms History Log Diagnostics
Battery Duration	Approximately 4 hours at 2LPM (pulse)	Approximately 4 hours at 2LPM (pulse)
Operating Environment	5 to 40^{o} C Altitude: 0-8000 ft RH: 5 – 95 %	5 to 40^{o} C Altitude: 0-9000 ft RH: 5 – 93 %
Shipping / Storage Conditions	Temperature: -20 to 60^{o}C, Keep Dry, Humidity: 0 - 95 % RH	Temperature: -20 to 60^{o}C, Keep Dry, Humidity: 0 - 93 % RH
Electrical	IEC 60601-1	AAMI ANSI ES60601-1

Attribute	Predicate Device: K073242 RS-00400	Proposed Device: GCE Zen-O™ RS-00500
Safety	IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2
Mechanical Safety	IEC 60601-1	IEC 60601-1
Chemical Safety	Not Applicable	Not Applicable
Thermal Safety	IEC 60601-1	IEC 60601-1
Biocompatibility	4 VOC's less than ambient	4 VOC's less than ambient
Standards Met	IEC 60601-1 IEC 60601-1-2 ISO 8359:1996 ASTM F-1464-93:2005	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
Type of Protection against electric shock	Type BF – Not for cardiac	Type BF – Not for cardiac
Safety Markings	UL	ETL

Comparison Discussion

Indications for Use –

The indications for use are equivalent for the proposed device when compared to the predicate – K073242 – Oxus Model RS-00400 POC.

> **Discussion –** The indications for use are equivalent to the predicate – K073242 – Oxus Model RS-00400 POC

Patient Population –

The patient populations are similar for the proposed device when compared to the predicate – K073242 – Oxus Model RS-00400 POC. Adult patients with chronic pulmonary diseases such as chronic bronchitis, emphysema, asthma, or lung cancer, those in the terminal stage of cancer, or any patient requiring supplemental oxygen.

> **Discussion –** The patient populations are equivalent to the predicate – K073242 – Oxus Model RS-00400 POC

Environment of Use –

The environment of use are equivalent for the proposed device when compared to the predicate – K073242 – Oxus Model RS-00400 POC.

> **Discussion –** The environment of use are equivalent to the predicate – K073242 – Oxus Model RS-00400 POC

Principle of Operation and Technology –

The design, components, and principle of operation of the POC, based on molecular sieve / pressure swing absorption technology, to draw ambient air, push it through a sieve bed, then utilize pressure swing absorption to convert the ambient air to pure oxygen have been shown to be equivalent to the predicate – K073242 – Oxus Model RS-00400 POC.

> **Discussion –** The GCE Zen-O™ POC design uses molecular sieve / Pressure Swing Adsorption (PSA) technology to deliver concentrated oxygen. A series of chambers and valves allows pressurized air to enter the sieve bed assembly, effectively separating nitrogen from the air. When one chamber is receiving pressurized air, the other is purging nitrogen back into the air. The cycle is repeated continuously. The concentrated oxygen created at each cycle is stored in a chamber to be delivered to a patient when the device detects a patient breath are equivalent to the predicate – K073242 – Oxus Model RS-00400 POC

The differences between the proposed device and predicate are:

- The GCE Zen-O™ Portable Oxygen Concentrator has additional capability compared to the Oxus Model RS-00400 as it can deliver in either pulse mode or continuous flow modes; however the oxygen producing operations are similar.

- The two products are different from each other as indicated in the comparison table below in size and weight. The subject device is a slightly heavier concentrator that provides both pulse and continuous flow delivery options.

The GCE Zen-O™ POC Model RS-00500 and the predicate device both meet the requirements related to performance and safety standards applicable to the portable oxygen concentrators and the differences noted in the comparison do not raise different questions of safety or effectiveness and thus we can conclude the proposed GCE Zen-O™ POC Model RS-00500 is substantially equivalent to the predicate, K073242 – Oxus Model RS-00400 POC.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the GCE Zen-O™ POC was conducted in accordance with the FDA Guidance Document “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA.

Particulate Matter 2.5 micron (PM2.5) testing, according to United States Environmental Protection Agency (EPA), was completed and the POC emitted a mean PM2.5 level less than the EPA PM2.5 level of 15 ug/m^3.

Inorganic gases (Ozone, CO2, and CO) were evaluated with no levels detected of CO2 or CO and Ozone concentration is less than the EPA allowed 0.050 ppm.

Patient contact with composite materials is limited to:

- Device enclosure,
- Handle,
- Battery, and
- Interface panel.

The route of exposure to these materials would be through incidental contact with the patient’s skin and does not contact the patient during normal device use.

The GCE Zen-O™ POC Model RS-00500 Medical Device Categorization per Annex A of ISO 10993-1:2009(E) for all composite material is:

- Category : External communicating device
- Contact : Tissue
- Duration : A – Limited (≤ 24 h)

The POC is considered tissue contacting for a duration of less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the GCE Zen-O™ POC. The system complies with the AAMI ANSI ES60601-1, IEC 60601-1, IEC 60601-1-6, 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 testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” 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.

Mechanical and acoustic testing

Functional Performance Testing has been performed on a production unit to demonstrate that the GCE Zen-O™ Portable Oxygen Concentrator will perform as intended and additionally to

demonstrate equivalency to the Oxus RS-00400 POC. The production unit was constructed of components of the final device configuration and meet performance specifications.

Testing was performed according to the performance standards listed above and internal test protocols to identify test methods.

Comparative Bench Testing

The GCE Zen-O™ Portable Oxygen Concentrator (POC) has been designed to be compliant with the requirements of recognized consensus standards for Oxygen Concentrators:

- ISO 80601-2-67 Particular requirements for basic safety and essential performance of oxygen conserving equipment
- ISO 80601-2-69 Particular requirements for basic safety and essential performance of oxygen concentrator equipment

Usability Studies

Usability testing was performed with 4 users on two devices, lay users and Healthcare Providers. Testing included the appropriate tasks based upon the risk analysis. Testing found that the design of the device and instructions for use were appropriate for the intended user groups.

Animal Study

Not applicable for this device

Clinical Studies

There was no clinical testing performed.

VIII. Conclusions

As detailed, the indications for use, patient population, environment of use, technology or principle of operation, and performance are substantially equivalent to the predicate.

The identified differences between the proposed GCE Zen-O™ POC Model RS-00500 and the predicate – K073242 – Oxus Model RS-00400 POC, allows us to conclude that there are no different questions of safety or effectiveness that raise new risks and thus the proposed device can be determined to be substantially equivalent.