May 31, 2023

Oxus, Inc.
% Paul Dryden
President
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K211056
Trade/Device Name: Refurbished Replacement Column (Sieve Bed)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: November 28, 2022
Received: November 28, 2022

Dear Paul Dryden:

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,

James J. Lee -S

James J. Lee, PhD
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)*
K211056

Device Name

Refurbished Replacement Column (Sieve Bed)

Indications for Use *(Describe)*

Refurbished Replacement Column (Sieve Bed) are regular replacement parts for Inogen One G3 Oxygen Concentrator.

The Inogen One Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Inogen One Oxygen Concentrator may be used in a home, institution, vehicles and various 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.

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510(k) Summary

Date Prepared:	31-May-23
Sponsor:	Oxus, Inc. 2046 Brown Rd. Auburn Hills, MI 48326
Sponsor Contact:	Ryan Lenarcic Quality & Regulatory Manager Tel - 248-475-0925
Submission Correspondent:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	Refurbished Replacement Column (Sieve Bed)
Common/Usual Name:	Replacement Sieve Bed for Portable Oxygen Concentrator
Classification Name:	Generator, Oxygen, Portable
CFR	CFR 868.5440
Product Code	CAW
Predicate Device:	K032818, Inogen One G3 Portable Oxygen Concentrator
Classification Name:	Generator, Oxygen, Portable
CFR	CFR 868.5440
Product Code	CAW

Device Description:
The subject device is a compatible replacement part of the Inogen One G3 portable oxygen concentrator, ("POC"). Standard portable oxygen concentrators generate oxygen from room air by use of a sieve bed that removes nitrogen, other gases and impurities from the room air and generates oxygen for patients requiring supplement oxygen.

These sieve beds must be replaced on a schedule in order to maintain the POC's ability to deliver the require % oxygen. The subject device is refurbished with existing Inogen One G3 components with a new sieve bed. The final product is equivalent to the Inogen one G3 replacement sieve bed cartridge.

Principle of Operation:
The composition of air (78% Nitrogen, 21% Oxygen and 1% other gases like Carbon Dioxide, Argon, etc.) clearly shows that air is mainly comprised of two gases: Nitrogen and Oxygen [together 99%]. If Nitrogen is removed from air, the primary gas remaining would be Oxygen with purity of about 90-95%. An Oxygen Concentrator uses this idea with the basic principle of Pressure Swing Adsorption (PSA) to deliver 90-95% pure oxygen. Since the subject device is a refurbished sieve bed utilizing the Inogen One G3 components with the sieve bed replenished.

Indications for Use:
Refurbished Replacement Column (Sieve Bed) are regular replacement parts for Inogen One G3 Oxygen Concentrator.

The Inogen One Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to

channel oxygen from the concentrator to the patient. The Inogen One Oxygen Concentrator may be used in a home, institution, vehicles and various mobile environments.

Patient Population:
Patients who are on supplemental oxygen and needs replacement sieve beds.

Environments of use:
Home, institution, vehicles and various mobile environments

Table 1 is a comparison – Subject Device vs. the Predicate, K032818 – Inogen G3 POC. Note that the comparison to the predicate is based upon available technical specifications.

Substantial Equivalence Discussion
The subject device utilizes similar components of the predicate sieve bed and has similar indications, technological characteristics, principles of operation and performance as the predicate Inogen One G3, K032818, replaceable sieve beds. The subject device does not raise different questions of safety and effectiveness compared to the predicate.

Non-clinical Testing
Performance testing demonstrated that the Oxus Refurbished sieve bed met its acceptance criteria. Testing included:

Bench
- Fill Volume
- Oxygen Purity over time per applicable parts of ISO 80601-2-69:2020 clause 201.12.1.103 (Medical electrical equipment — Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment) testing was done at intervals up to 8 hours with performance compared to the predicate.
- Leakage
- Package integrity

Biocompatibility
- ISO 18562-2:2017 – Particulate Matter compared with predicate and subject device after 10 cleaning / refurbishing cycles
- ISO 18562-3:2017 – VOC compared with predicate and subject device after 10 cleaning / refurbishing cycles
- Inorganic gases – CO, CO_2, Ozone
- Toxicological Risk Assessment

Substantial Equivalence Conclusion
The Oxus Refurbished sieve bed has similar intended use and indications, technological characteristics, principles of operation and performance as the predicate.

The performance testing supports substantial equivalence to the Inogen One G3 replacement sieve bed cartridges, K032818.

Table 1 – Comparison – Subject vs. Predicate

	Subject Device **Oxus Refurbished Sieve Bed**	**Predicate Device** **Inogen One G3 – K032818**	**Comparison**
Manufacturer	Oxus	Inogen	
Classification	21 C.F.R. § 868.5440 Portable Oxygen Generator Product Code – CAW, (Class II)	21 C.F.R. § 868.5440 Portable Oxygen Generator Product Code – CAW, (Class II)	Similar Subject device is only the replaceable sieve bed cartridge
Fundamental scientific technology	Sieve beds operate as part of the basic principle of Pressure Swing Adsorption (PSA) to deliver 90-95% pure oxygen.	Sieve beds operate as part of the basic principle of Pressure Swing Adsorption (PSA) to deliver 90-95% pure oxygen.	Similar
Indications for Use	Refurbished Replacement Column (Sieve Bed) are regular replacement parts for Inogen One G3 Oxygen Concentrator. The Inogen One Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Inogen One Oxygen Concentrator may be used in a home, institution, vehicles and various mobile environments. Has replaceable sieve bed cartridges.	The Inogen One Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Inogen One Oxygen Concentrator may be used in a home, institution, vehicles and various mobile environments. Has replaceable sieve bed cartridges	Similar as the subject device is only the replaceable sieve bed cartridge and not the system.
User Installed	User can order replacements and install	User can order replacements and install	Same
Environment of Use	Home	Home	Similar
Patient	Patients on supplemental oxygen	Patients on supplemental oxygen	Similar

Population			
	Subject Device **Oxus Refurbished Sieve Bed**	**Predicate Device** **Inogen One G3 – K032818**	**Comparison**
Models	High flow rate – 1 to 5 Low flow rate – 1 to 4	High flow rate – 1 to 5 Low flow rate – 1 to 4	Same
Components of Replaceable Sieve bed	Recycled Sieve tube, Wave spring, Sieve CapNew Plastic diffuser, O-rings, Seal, Zeolite Alumina, Label	Sieve tube, Wave spring, Sieve Cap, Plastic diffuser, O-rings, Seal, Zeolite, Alumina, Label	The parts are similar and each recycled cartridge is tested
Biocompatibility	Externally Communicating, Tissue Permanent (> 30 days) ISO 18562-2 – PM 2.5 and 10 microns ISO 18562-3 – VOC Inorganic – CO, CO_2, Ozone Toxicological Risk Assessment	Externally Communicating, Tissue Permanent (> 30 days) Testing not known	Similar patient contact and testing to current standards Testing performed post-recycling vs. predicate
Performance Testing	Oxygen Purity >= 90% Purity at Setting 5 at various temperature, humidity and altitude conditions Bed Leak Rate < 0.5 lpm at ~ 28.5 PSIG Packaging integrity Labeling	Oxygen Purity >= 90% Purity at Setting 5 Bed Leak Rate not stated	Similar