August 19, 2022

CareOx, LLC
% Paul Dryden
Consultant
ProMedic Consulting, LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K213933
Trade/Device Name: Percent Oxygen Sensors
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: Class II
Product Code: CCL
Dated: July 20, 2022
Received: July 21, 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,

for Todd Courtney
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)*
K213933

Device Name
Percent Oxygen Sensors

Indications for Use *(Describe)*
Percent Oxygen Sensors are intended to replace the original oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Date: August 16, 2022

Sponsor:

CAREOX®, LLC
103 Carnegie Center Ste. 300
Princeton, NJ 08540

Tel - 609.524.2540

Sponsor Contact: Young Kim – CEO

Submission Correspondent: Paul Dryden
ProMedic, LLC

Proprietary or Trade Name: Percent Oxygen Sensors

Common/Usual Name: Oxygen Sensors

Regulation Number: 21CFR 868.1720
Regulation Code: Analyzer, Gas, Oxygen, Gaseous-Phase
Product Code: CCL
Regulatory Class: II

Predicate Device: K952736 Analytic Industries Percent Oxygen Sensors

Device Description:
The subject device is a family of Medical Oxygen Sensors which may be used as industry replacement types with various medical inspired-oxygen measuring devices.

The oxygen sensors are all electrochemical galvanic type devices. The difference between models is merely the physical shape of the external housing (the basic oxygen sensor is often time encapsulated in a secondary housing), signal connection, signal output and the response time.

The family of oxygen sensors concept extends to OEM manufacturers of anesthesia and respiratory therapy equipment. Again, the difference between models is merely the physical shape of the external housing (the basic oxygen sensor is often time encapsulated in a secondary housing), signal connection, signal output and the response time in order for the OEM to exercise a degree of control over the recurring replacement of oxygen sensors.

Indications for Use:
Percent Oxygen Sensors are intended to replace the original oxygen-sensing components of an oxygen analyzer that measures oxygen concentration in breathing gases.

Patient Population: The sensor follows the population of the equipment for which it is attached.

Environment of Use: Hospital/institutional, pre-hospital, industrial and home settings.

Substantial Equivalence Discussion:
The subject devices are manufactured by Analytical Industries Inc. and were cleared under K952736. CareOx, the sponsor of this submission is purchasing final, finished oxygen sensors from Analytical Industries Inc. with the private label of CareOx.

Indications – Equivalent to the predicate

Technology – The technology is identical

Principal of Operation – The principal of operation is identical

Operating specifications – Equivalent

Environment of Use – Similar

Patient Population – Similar

Non-clinical Testing

We have performed the applicable test from ISO 80601-2-55.

These tests includes:
Accuracy
Precision
Specificity
Sensitivity
Linearity
Range
Response time

Differences:
There are no differences between the proposed device and the predicate device.

Table of Comparison to Predicate

Attribute	Predicate Analytic Industries Percent Oxygen Sensors	Subject Device CareOx	Equivalency to at least one or both devices
K# Product Code Classification Name	K952736 CCL Analyzer, Gas, Oxygen, Gaseous-Phase	TBD CCL Analyzer, Gas, Oxygen, Gaseous-Phase	Similar
Indications for Use	Percent Oxygen Sensors are intended to replace the original oxygen-sensing components of an oxygen analyzer that measures oxygen concentration in breathing gases.	Percent Oxygen Sensors are intended to replace the original oxygen-sensing components of an oxygen analyzer that measures oxygen concentration in breathing gases.	Similar
Environments of use	Replacement sensor for equipment that provides inspired oxygen concentrations	Replacement sensor for equipment that provides inspired oxygen concentrations	Similar
Principle of operation	Electrochemical galvanic	Electrochemical galvanic	Similar
Prescriptive	Yes	Yes	Similar
Service Life	The life of sensor is based on the Faraday's law of electrolysis, i.e., the current generated by the sensor per unit volume of oxygen and the amount of the lead anode in the sensor determines the life of the sensor. Only 70% of theoretically calculated sensor life is used to claim the useful life of the sensor. For example, if theoretical life is calculated as 90 months, the claimed life of the sensor would be 63 months.	The life of sensor is based on the Faraday's law of electrolysis, i.e., the current generated by the sensor per unit volume of oxygen and the amount of the lead anode in the sensor determines the life of the sensor. Only 70% of theoretically calculated sensor life is used to claim the useful life of the sensor. For example, if theoretical life is calculated as 90 months, the claimed life of the sensor would be 63 months.	Similar

Substantial Equivalence Conclusion:

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.