November 21, 2023

Southmedic Inc.
Tish Whitehead
Vice President of Regulatory Affairs &
New Product Development
50 Alliance Blvd.
Barrie, Ontario L4M 5K3
Canada

Re: K222511
Trade/Device Name: Oxy2Pro
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: September 29, 2023
Received: September 29, 2023

Dear Tish Whitehead:

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.

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 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)*
K222511

Device Name
Oxy2Pro

Indications for Use *(Describe)*
Oxy2Pro is a single patient, disposable procedural mask with access for the insertion of oral scopes, probes, or tubes, delivery of supplemental oxygen and monitoring breathing by providing a means to sample exhaled CO2. It is for non-intubated, adult patients who are breathing spontaneously.

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.

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510(k) Summary

Company:	Southmedic Inc. 50 Alliance Blvd. Barrie, Ontario, Canada L4M 5K3
Official Contact:	Tish Whitehead P: (705) 720-1902 F: (705) 728-6537
Date Prepared:	11/20/2023
Trade Name:	Oxy_2Pro
Common Name:	Gas sampling oxygen mask
Classification:	Product Code: CCK Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase Class II per 21 CFR 868.1400 Anesthesiology
Predicate Device:	Panoramic Oxygen Mask (POM) – K172365 POM Medical, LLC
Device Description:	The Southmedic Oxy_2Pro is designed to have a flexible, thin membrane that is intended to be breached when requiring oral access for scope entry. This slitted membrane is intended to allow the mask to return to a closed-mask functionality after having been used with a scope. This device is to be used in conjunction with FDA cleared capnographs.
Intended Use:	The Oxy_2Pro is a single patient, disposable procedural mask with access for the insertion of oral scopes, probes, or tubes, delivery of supplemental oxygen and monitoring breathing by providing a means to sample exhaled CO_2. It is for non-intubated, adult patients who are breathing spontaneously.

Predicate Device Comparison:

Table 1: Predicate Device Comparison Table

Description	Subject Device	Predicate Device (K172365)	Comments
Indications for Use	The Oxy_2Pro is a single patient, disposable procedural mask with access for the insertion of oral scopes, probes, or tubes, delivery of supplemental oxygen and monitoring breathing by providing a means to sample exhaled CO2. It is for non-intubated, adult patients who are breathing spontaneously.	The Panoramic Oxygen Mask (POM) is a single patient, disposable device intended for delivering supplemental oxygen and monitoring expired gases from the patient, with ports to allow the clinician to insert scopes, probes, or tubes. It is for non-intubated, spontaneously breathing patients greater than 30kg.	Same
Patient Population	Non-intubated, adult patients who are breathing spontaneously.	Non-intubated spontaneously breathing patients. Greater than 30 kg	Similar; the predicate device is available in adult and pediatric sizes. This comparison is only made to the adult size.
Environments of Use	Locations where procedures are performed where the patient requires supplemental oxygen, monitoring of exhaled gases and scope access. Hospital, sub-acute, clinic, physician offices, pre-hospital	Locations where procedures are performed where the patient requires supplemental oxygen, monitoring of exhaled gases and scope access. Hospital, sub-acute, clinic, physician offices, pre-hospital	Same
Duration of Use	Single patient, disposable	Single patient, disposable	Same
Prescriptive	Yes	Yes	Same
Mode of Operation	Oxygen delivery through standard oxygen supply tubing and simultaneous exhaled gas monitoring via a gas sampling line connected from mask to capnography or oxygen only delivery. Slit access membrane	Oxygen delivery through standard oxygen supply tubing and simultaneous exhaled gas monitoring via a gas sampling line connected from mask to capnography or oxygen	Similar; Oxy_2Pro does not feature a universal size inlet but it achieves the same performance through the diffuser sleeve and insert without the need for additional adaptors.

Southmedic Incorporated
Head Office: 50 Alliance Blvd., Barrie, Ontario, Canada L4M 5K3
1-705-726-9383 1-800-463-7146 Fax: 1-705-728-9537
www.southmedic.com ISO 13485

Description	Subject Device	Predicate Device (K172365)	Comments
	allowing for introduction of a scope. Oxygen and sampling tube are connected to mask via a rotatable elbow positioned in front of the face.	only delivery. Slit access ports allowing for introduction of a scope. Universal size inlet allows for removal or insertion of high or medium concentration adaptor, located to the side of the front of the mask. The sampling line is connected on the opposite side.	
Components which may be supplied or packaged with the mask	Standard oxygen tubing (connected to mask) with universal connector Gas sampling line	Standard oxygen tubing with universal connector Gas sampling line Oxygen rebreather bag	Similar; Oxy_2Pro does not feature a universal size inlet with a rebreather bag but it achieves the same performance through the diffuser sleeve and insert without the need for additional adaptors.
Gas sampling connections	Male Luer and Female Luer	Luer slip fit	Similar; Southmedic shall offer both a female and male luer sampling line to accommodate different capnography equipment.
Sizes	Adult	Adult	Oxy_2Pro is only available in adult size; comparison only made to adult predicate.

Description	Subject Device	Predicate Device (K172365)	Comments
Profile	Over the nose/mouth	Over the nose/mouth; aluminum nose strip	Similar; Oxy_2Pro does not feature an aluminum nose strip but instead is shaped to sit on the nose. This difference does not impact performance.
Face Strap	Yes	Yes	Same
Internal Volume	Adult – 230 ml	Adult – 198 ml	Similar; Oxy_2Pro has a somewhat larger volume but it is not expected to affect the intended use.
Access Membranes/ Ports and Maximum Instrument size	Oral Access Membrane – 58 mm x 42 mm	Oral port – 60 mm ID / 20 mm OD Nasal – 36 mm ID / 12 mm OD	Similar; Oxy_2Pro contains an oral access membrane to allow for the introduction of instruments while delivering oxygen and sampling expired gases. The absence of a nasal port does not impact the intended use.
Vents	Open ports allow room entrainment to prevent rebreathing	One-way valves to prevent rebreathing	Similar; the difference in methodology does not affect performance or intended use
Oxygen Flow Rates	Flow rates from 5 liters per minute to 15 liters per minute	Medium Concentration: 6-8 liters High Concentration: 10-15 liters	Same; devices offer the same flow rate range
% FiO2	Testing was completed under simulated conditions at various flow rates.	Testing was completed under simulated conditions at various flow rates.	Same; Oxy_2Pro was not significantly less than the predicate.

Description	Subject Device	Predicate Device (K172365)	Comments
% CO2 Accuracy	Testing was completed under simulated conditions with true baseline $EtCO_2$ at 5%, at various flow rates.	Testing was completed under simulated conditions with true baseline $EtCO_2$ at 5%, at various flow rates.	Same; Oxy_2Pro was not significantly less than the predicate.
Materials	Mask: Clear Polyvinylchloride Elbow and Sleeve: Acrylic Insert: Polypropylene	Mask: Clear Polyvinylchloride	Similar
Biocompatibility	Surface contacting for a limited duration (<24 hours). Gas pathway contacting for a limited duration (<24 hours). Testing includes: Cytotoxicity (ISO 10993-5:2009) Sensitization (ISO 10993-10:2010 Intracutaneous/Irritation (ISO 10993-10:2010) Emissions of particulate matter (ISO 18562-2:2017) Emissions of volatile compounds (VOCs) (ISO 18562-3:2017)	Externally communicating: Tissue contact, surface communicating, and skin contact for a limited duration of use (<24 hours). Testing included: Cytotoxicity (ISO 10993-5:2009) Sensitization (ISO 10993-10:2010 Intracutaneous/Irritation (ISO 10993-10:2010) Acute Systemic Toxicity (ISO 10993-11:2017)	Similar; devices have a similar biological categorization. Differences in testing endpoints may be attributed to the application of ISO 10993-1 and ISO 18562.
Storage	Standard warehouse conditions	-20º to +50ºC	Similar
Device Classification	Class II Product code - CCK	Class II Product code - CCK	Same

Substantial Equivalence Discussion:
The Oxy_2Pro Mask is considered substantially equivalent to the predicate Panoramic Oxygen Mask (POM), by POM Medical (510k holder, K172365) based on the following discussion. In making this determination, Southmedic followed the FDA's Guidance entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (Document issued on: July 28, 2014) and the detailed flowchart provided in Appendix A. 510(k) Decision-Making Flowchart.

Intended Use: The Oxy_2Pro is a single patient, disposable procedural mask with access for the insertion of oral scopes, probes, or tubes, delivery of supplemental oxygen and monitoring breathing by providing a means to sample exhaled CO_2. It is for non-intubated, adult patients who are breathing spontaneously. Both devices provide supplemental oxygen and monitoring of exhaled gases, with oral scope access and are to be used in similar environments of use.

The predicate is available in pediatric and adult sizes and features an additional nasal access port. The adult version of the predicate was used for comparison testing. Regardless of model, both sizes have the same intended use. The nasal access port in the predicate facilitates nasal scope/probe entry. This may lead to additional indications provided by the predicate, however, the intended use and indications per the predicate labeling does not differentiate between the nasal or oral option. Per the labeling, the Oxy_2Pro and predicate device have the same intended use and the same environments of use when compared within the same indication. The difference of the predicate device having a nasal access port should not affect oxygen delivery and sampling performance.

Technology: The devices have similar sampling line luer and oxygen tubing technology, and feature oral access ports/membranes for scope entry. The oxygen tubing is connected to the oxygen source using a universal connector, and the sampling line is connected to the capnography equipment. The Oxy_2Pro mask is made of a clear polyvinylchloride material which is the same material as the predicate.

Oxy_2Pro's oxygen and sampling lines are connected to the mask via a rotatable elbow positioned at the front of the face. Oxygen is delivered through a diffuser sleeve and insert that directs the oxygen towards the nose and mouth. Carbon dioxide is sampled through this same diffuser.

The predicate device features a universal size inlet to allow for the removal or insertion of a high or medium concentration adaptor, which is located to the side of the front of the mask. Oxygen is delivered through this adaptor. The sampling line is connected to the opposite side of the mask.

The safety and performance of the Oxy_2Pro and predicate device are similar, as shown in the testing summary below. The differences in technology do not affect device performance and safety with respect to oxygen delivery and $EtCO_2$ sampling.

Testing summary:

Biocompatibility and Materials:

The Oxy_2Pro and predicate have similar biocompatibility categorizations. The Oxy_2Pro has been assessed as a limited contact duration mask against the following requirements and endpoints: ISO 18562-2 Emissions of particulate matter; ISO 18562-3 Emissions of volatile compounds (VOCs); ISO 10993-5 Cytotoxicity; ISO 10993-10 Sensitization; ISO 10993-10:2010 Intracutaneous/Irritation. Differences in testing endpoints are attributed to the application of ISO 10993-1 and ISO 18562. The primary material for both devices is clear polyvinylchloride.

Performance Testing:

Accredited third-party testing was completed to evaluate the ability to deliver FiO_2 and sample $EtCO_2$ relative to the predicate device.

	Oxy_2Pro		**Predicate (K172365)**	
Oxygen Flow Rate	**FiO2**	**ETCO2**	**FiO2**	**ETCO2**
5 l/min	53.3%	6.13%	N/A	N/A
8 l/min	64.0%	4.87%	52.3%	4.03%
10 l/min	64.7%	4.70%	48.3%	4.17%
12 l/min	67.3%	3.77%	54.7%	3.30%
15 l/min	72.3%	3.70%	52.0%	3.53%

Test conditions: Respiratory Rate: 12, Tidal Volume: 500, Inspiratory:Expiratory Ratio: 1:1, Baseline true $EtCO_2$ 5%. Acronyms: l/min is liters per minute, FiO_2 is fraction of inspired oxygen, $EtCO_2$ is end tidal carbon dioxide

The results demonstrated that the Oxy_2Pro mask was not statistically significantly less than the predicate for FiO_2 or $EtCO_2$ at the tested flow rates, meeting the acceptance criteria.

In conclusion, substantial equivalence is demonstrated between the Oxy_2Pro mask and the predicate device. The differences observed do not impact performance and safety per the intended use of supplemental oxygen delivery and $EtCO_2$ sampling.