April 19, 2018

POM Medical, LLC
% Paul Dryden
Consultant
ProMedic, LLC
131 Bay Point Dr NE
St. Petersburg, Florida 33704

Re: K172365
Trade/Device Name: Panoramic Oxygen Mask (POM)
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: March 17, 2018
Received: March 20, 2018

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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172365

Device Name

Panoramic Oxygen Mask (POM)

Indications for Use *(Describe)*

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 30 kg.

Type of Use *(Select one or both, as applicable)*

XX 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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Company:	POM Medical, LLC 1230 Madera Rd., Suite 5, Box 101 Simi Valley, CA 92065
Official Contact:	Jeff Voss, VP Operations Tel - (855) 766-0202
Proprietary or Trade Name:	Panoramic Oxygen Mask (POM)
Common/Usual Name:	Gas sampling oxygen mask
Classification Name:	21 CFR 868.1400 Procode – CCK Analyzer, gas, carbon-dioxide, gaseous phase Class II
Predicate Device:	K133806 – Monitored Mask, M1 Capnography mask CapnoVue Scope

Device Description:
The Panoramic Oxygen Mask (POM) is a multi-port mask that serves several functions:

- A standard oxygen mask for when a patient requires supplemental oxygen
- Sampling of exhaled gases for monitoring, typically end-tidal CO_2
- Additional ports (membranes) to allow for most types of scopes, probes, and tubes to be inserted while still delivering supplemental O_2 and sampling exhaled gases.

The design of the POM's oral or nasal membranes allow access of a scope and are soft and pliable to help maintain the oxygen concentration to the patient while having scopes, etc. inserted through these oral or nasal membranes.

Indications for Use:
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 30 kg.

Patient Population:
For non-intubated, spontaneously breathing patients greater than 30 kg.

Environment of Use:
Locations where procedures are performed where the patient requires supplemental oxygen, monitoring exhaled gases, and scope access

Hospital, sub-acute, clinic, physician offices, pre-hospital.

Contraindications:
None.

Predicate Device Comparison - Table 1 – Comparison to the Predicate

Attributes	**Proposed** **POM Panoramic Oxygen Mask**	**Predicate** **Monitor Mask – K133806** **M1 Capnography mask (Scope)**	**Comments**
Indications for Use	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.	The M1 Capnography Mask is a single-use device intended for delivering supplemental oxygen and monitoring exhaled carbon dioxide in non-intubated spontaneously breathing patients. Standard oxygen tubing and two female luer ports for gas sample line attachment are included.	Both provide - supplemental oxygen - monitoring of exhaled gases Subject device provides - access port(s) for scopes (CapnoVue Scope model)
Patient Population	non-intubated spontaneously breathing patients Greater than 30 kg	non-intubated spontaneously breathing patients Child and adult	Similar
Environment of Use	Locations where procedures are performed where the patient requires supplemental oxygen, monitoring 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 exhaled gases Hospital, sub-acute, clinic, physician offices, pre-hospital	Scope access for the subject device
Duration of Use	Single patient, disposable	Single patient, disposable	Similar
Prescriptive	Yes	Yes	Similar
Mode of Operation	O_2 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 ports allowing for introduction of a scope	O_2 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 ports allowing for introduction of a scope are provided in the CapnoVue Scope model

Attributes	**Proposed** **POM Panoramic Oxygen Mask**	**Predicate** **Monitor Mask – K133806** **M1 Capnography mask (Scope)**	**Comments**
Components which may be supplied or packaged with the mask	Standard oxygen tubing Gas sampling line	Standard oxygen tubing Gas sampling line	Similar
Gas sampling connection	Luer slip fit	Luer lock	Similar Both connector type accommodate standard gas sampling luer fittings
Sizes	Child Adult	Child Adult	Similar
Profile	Over the nose / mouth	Over the nose / mouth	Similar
Face strap	Yes	Yes	Similar
Performance			
Internal volume	Child – 93 ml Adult – 198 ml	Child – 73 ml Adult – 159 ml	The difference in internal volume does not affect performance of oxygen delivery or monitoring of exhaled gases
Access Ports and Maximum instrument size	Oral port – 60 mm ID / 20 mm OD Nasal – 36 mm ID / 12 mm OD	Not available	Access port allows introduction of instruments while delivering supplemental oxygen and sampling expired gases
Entrainment Vents	One-way valves to prevent rebreathing	Open vents allowing room entrainment	Without the one-way valves the exhaled gas monitoring performance is reduced. For the intended use the designs are similar. There are oxygen masks marketed as non-rebreathing mask with one-way valves to prevent rebreathing. (Teleflex Non-rebreathing mask) This does not raise different questions of safety or effectiveness.

Attributes	**Proposed** **POM Panoramic Oxygen Mask**	**Predicate** **Monitor Mask – K133806** **M1 Capnography mask (Scope)**	**Comments**
%CO_2 accuracy and Respiration rate	Testing was done at different simulated patient settings for breath rate, Tidal Volume at different CO_2 concentrations with waveforms .		The results showed similar performance with the proposed device.
Biocompatibility	External Communicating (indirect) Tissue contact And Surface Communicating (direct) Skin contact 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)	External Communicating (indirect) Tissue contact And Surface Communicating (direct) Skin contact Limited duration of use (< 24 hours)	Similar
Storage Shelf-life Effects of Aging	-20º to + 50ºC 3 years real-time aging and shelf-life No effects of aging on performance	Not specified	Testing supports the claim

Substantial Equivalence Discussion

The POM is viewed as substantially equivalent to the predicate device (K133806 - M1 Capnography mask) based on the following discussions:

Indications –

- The intended use is to provide supplemental oxygen, monitor exhaled gases, and provide scope access is similar to the predicate.

Discussion – Both provide supplemental oxygen, monitoring of exhaled gases The differences of the subject device having access port(s) for scopes or instruments has been shown to not affect performance related to supplemental oxygen delivery and $EtCO_2$ sampling.

Patient Population and environment of Use –

- The intended population is non-intubated spontaneously breathing patients in locations where procedures are performed that the patient may require supplemental oxygen, monitoring of exhaled gases and scope access.
- There are 2 sizes - Child and adult mask

Discussion – The population is similar to the predicate Monitor Mask – K133806 - M1 Capnography mask.

Technology –

- Identical technology of utilizing a luer fitting to connect gas sampling lines,
- This device modifies existing masks with ports for scope access.

Discussion – The technology is similar to the predicate Monitor Mask – K133806 - M1 Capnography mask.

Differences –

The subject device offers access ports for scopes while the mask sits on the patient face. This technological characteristic is a combination of supplemental O2 and CO2 sampling facilitated by cannulas, which still allows scopes to access the patient airway. While access ports are different technological characteristic, the risk is the inability to use scopes to access airway. Labeling is provided to ensure compatibility of scopes with this device for airway access.

The differences between the predicate and the proposed device do not impact the performance of the device for supplemental oxygen delivery and $EtCO_2$ sampling. These differences do not raise different questions of safety or effectiveness.

Non-clinical performance testing

We have performed non-clinical comparative performance testing that included:

- Internal volume
- Evaluation of ability to measure $EtCO_2$ and Respiration Rate are various simulated patient settings typical of pediatric and adult users.
- Storage, Drop and Aging
- Biocompatibility

Biocompatibility / Materials –

The materials in patient / drug contact have been tested they are characterized as:

- External Communicating (Indirect gas pathway), Tissue / Bone / Dentin communicating, And
- Surface Contact, Skin,
- Duration of Use – limited (< 24 hours)

We performed the following tests with guidance from ISO 10993-1 and the results were acceptable.

- Cytotoxicity – ISO 10993-5:2009
- Sensitization – ISO 10993-10:2010
- Irritation (for surface contact materials) – ISO 10993-10:2010
- Acute Systemic Toxicity – ISO 10993-11:2017

Discussion - The materials used in the subject device are familiar and standard materials utilized in devices for this intended use.

Bench / Performance testing -

We performed comparative performance testing the tests included:

- Internal volume
- Evaluation of ability to measure $EtCO_2$ and Respiration Rate are various simulated patient settings typical of pediatric and adult users.
- Biocompatibility of Materials
- Mechanical Drop test
- Effects of Aging on Performance
- Environmental Testing / Shelf-life
- ISO 594 – Luer connector

Tables 2 and **3** presents a summary of the testing performed.

Table 2 – Summary of Comparative Testing – Adult Size

		POM		**Predicate M1**	
Adult		**$EtCO_2$ Closed / Inserted**	**RR Closed / Inserted**	**$EtCO_2$**	**RR**
Test conditions	**BPM – 12, TV – 500 ml**				
5% CO_2	O_2 Flow – 1 Lpm	7.37% / 6.57%	12 /12	6.43%	12
	O_2 Flow – 8 Lpm	5.17% / 4.78%	12 /12	2.50%	12
1% CO_2	O_2 Flow – 1 Lpm	1.40%	12	1.20%	12
	O_2 Flow – 8 Lpm	1.00%	12	0.47%	12
	BPM – 20, TV – 300 ml				
5% CO_2	O_2 Flow – 1 Lpm	8.23% / 7.07%	20 /20	6.77%	20
	O_2 Flow – 8 Lpm	6.17% / 4.40%	20 /20	3.37%	20
1% CO_2	O_2 Flow – 1 Lpm	1.63%	20	1.27%	20
	O_2 Flow – 8 Lpm	1.13%	20	0.60%	20
Internal Volume		198 ml		159 ml	

Table 3 – Summary of FiO_2 Testing – Adult Size

		POM
Adult		**FiO_2 Closed**
Test conditions	**BPM – 12, TV – 400 ml**	

4% CO_2	O_2 Flow – 8 Lpm	77.6%
	O_2 Flow – 10 Lpm	83.4%
	O_2 Flow – 12 Lpm	87.0%

Table 4 – Summary of Comparative Testing – Pediatric size

		POM			Predicate M1	
Pediatric		**$EtCO_2$ Closed / Inserted**	**RR Closed / Inserted**	**FiO_2 Closed / Inserted**	**$EtCO_2$**	**RR**
Test conditions		**BPM – 12, TV – 500 ml**				
5% CO_2	O_2 Flow – 1 Lpm	6.40% / 6.13%	12 /12	25.0% / 24.33%	6.17%	12
	O_2 Flow – 8 Lpm	3.40% / 3.17%	12 /12	48.67% / 49.0%	4.07%	12
1% CO_2	O_2 Flow – 1 Lpm	1.10%	12		1.07%	12
	O_2 Flow – 8 Lpm	0.73%	12		0.77%	12
		BPM – 20, TV – 300 ml				
5% CO_2	O_2 Flow – 1 Lpm	6.40% / 6.23%	20 /20	23.67% / 24.67%	6.03%	20
	O_2 Flow – 8 Lpm	3.10% / 2.23%	20 /20	56.0% / 56.33%	3.97%	20
1% CO_2	O_2 Flow – 1 Lpm	1.23%	20		1.17%	20
	O_2 Flow – 8 Lpm	0.70%	20		0.77%	20
Internal Volume		93 ml			73 ml	

The results demonstrated that the device is substantially equivalent.

Discussion of Differences and Substantial Equivalence Conclusion -
The differences in:

- Access ports
  - While access ports are different technological characteristic, the risk is the inability to use scopes to access airway. Labeling is provided to ensure compatibility of scopes with this device for airway access.
  - Access ports impact on monitoring is characterized
- Internal volume
  - While the internal volume of the mask is different the measured results show that the difference does not influence the measured performance.
- One-way valves for non-rebreathing
  - There are standard oxygen masks which contain one-way valves to prevent rebreathing.

These differences do not raise different questions of safety or effectiveness.

In conclusion, the comparison to the predicate for features, indications for use, population, and comparative testing across the range of oxygen flow, simulated patient conditions for both adult and pediatrics, exposed to different CO_2 levels demonstrated that both devices provide representative measurement of $EtCO_2$ and respiratory rate and their respective waveforms were similar.

The results demonstrate equivalence in performance.