November 16, 2022

Engineered Medical Systems Inc.
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K220533
Trade/Device Name: Endoscopy Oxygen Mask
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: October 17, 2022
Received: October 17, 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, Ph.D.
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 on last page.

510(k) Number *(if known)*

K220533

Device Name

Endoscopy Oxygen Mask

Indications for Use *(Describe)*

The Endoscopy Oxygen Mask 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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510(k) Summary

EMS

Date Prepared:	16-Nov-2022
Sponsor:	Engineered Medical Systems, Inc. 2055 Executive Dr. Indianapolis, IN 46241 Tel – 317-246-5500
Official Contact:	Tami Lefevers – senior QA/RA Manager
Proprietary or Trade Name:	Endoscopy Oxygen Mask
Common/Usual Name:	Oxygen mask with Gas sampling
Classification Name:	Product Code – CCK – Analyzer, gas, carbon-dioxide, gaseous phase
Predicate Device:	Panoramic Oxygen Mask (POM) - K172365
Common/Usual Name:	Oxygen mask with Gas sampling
Classification Name:	Product Code – CCK – Analyzer, gas, carbon-dioxide, gaseous phase

Device Description: The Endoscopy Oxygen Mask is a multi-port mask that **s**erves 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.

Principle of Operation: The subject device allows for O_2 delivery through standard oxygen supply tubing and simultaneous exhaled gas monitoring via a gas sampling line connected from mask to capnography. It may also be used for supplemental oxygen only delivery.

Slit access ports allowing for introduction of a scope, tubing, etc. by the healthcare professional.

Indications for Use: The Endoscopy Oxygen Mask 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.

Table 1 - Comparison of Subject vs. Predicate

	Predicate Panoramic Oxygen Mask (POM) POM Medical, LLC	Subject device Endoscopy Oxygen Mask Engineered Medical Systems, Inc.	Comparison
K#	K172365	TBD	N/A
Product Code	CCK	CCK	Similar
CFR	21 CFR 868.1400	21 CFR 868.1400	Similar
Classification	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	Similar
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.	The Endoscopy Oxygen Mask 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.	Similar
Patient Population	Non-intubated spontaneously breathing patients Adults to Children	Non-intubated spontaneously breathing patients Adults to Children	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, and scope access Hospital, sub-acute, clinic, physician offices, pre-hospital	Similar
Duration of Use	Single patient, disposable, <24 hours	Single patient, disposable, <24 hours	Similar
Perspective	Yes	Yes	Similar
Mode of Operation	O2 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	O2 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	Similar

	Predicate Panoramic Oxygen Mask (POM) POM Medical, LLC	Subject device Endoscopy Oxygen Mask Engineered Medical Systems, Inc.	Comparison
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 slip fit	Similar
Sizes	Child and Adult	Adult	Currently one size
Profile	Over the nose / mouth	Over the nose / mouth	Similar
Face strap	Yes	Yes	Similar
Performance			
Internal volume	Child – 93 ml Adult – 198 ml	Adult – 314 ml	The difference in internal volume does not impact comparative performance
Entrainment Vents	One-way valves to prevent rebreathing	One-way valves to prevent rebreathing	Similar
%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 performing better, but no claim is being made on performance other than equivalence.	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 performing better, but no claim is being made on performance other than equivalence.	Similar comparative testing results
Biocompatibility	External Communicating (indirect), Tissue contact And Surface Communicating (direct), Skin contact Limited duration of use (< 24 hours) ISO 10993-5 ISO 10993-10 ISO 18562-2	External Communicating (indirect), Tissue contact And Surface Communicating (direct), Skin contact Limited duration of use (< 24 hours)	Similar
Shelf-life **Effects of Aging**	3 years real-time aging and shelf-life No effects of aging on performance	1 year accelerated age testing No effects of aging on performance	Similar

Difference Between Subject and Predicate

The differences are:

- The FiO_2 results are similar across the range of tests, any differences do not have a pre-defined clinical criteria. Relative performance values are provided in the labeling as guides for the clinician during use. There is always additional monitoring being utilized, i.e., pulse oximeters for SpO_2 and expired gas monitors which would be used by the clinician.
- The larger internal volume of the subject mask provides larger access area to the clinician, while any differences in performance do not raise new safety or effectiveness concerns, thus the subject device can be found equivalent.

Substantial Equivalence Discussion

The Endoscopy Oxygen Mask is viewed as substantially equivalent to the predicate Panoramic Oxygen Mask (POM) – K172365.

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, and access port(s) for scopes.

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.

Discussion – The population is similar to the predicate Panoramic Oxygen Mask (POM) – K172365.

Technology –

- Similar technology of utilizing a luer fitting to connect gas sampling lines and having ports for scope access

Discussion – The technology is similar to the predicate Panoramic Oxygen Mask (POM) – K172365

Non-clinical 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 testing was conducted per International Standard Organization (ISO) 10993-1 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process and included cytotoxicity testing (MEM elution), sensitization (guinea pig maximization), intracutaneous reactivity, acute systemic toxicity, and material mediated pyrogenicity testing. In addition, particulate matter testing was performed per ISO 18562-2 Biocompatibility evaluation of breathing gas pathways in healthcare applications-Part 2: Tests for emissions of particulate matter

Substantial Equivalence Conclusion

The FiO_2 results are similar across the range of tests, this performance does not have a pre-defined clinical criteria. These are reported relative performance values in the labeling as guides for the clinician during use. There is always additional monitoring being utilized, i.e., pulse oximeters for SpO_2 and expired gas monitors which would be used by the clinician.

These differences do not raise new concerns of safety or effectiveness. The comparison to the predicate for features, indications for use, population, and comparative testing across the range of oxygen flow, simulated patient conditions, 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.