



December 6, 2024

Molecular Products Ltd.  
% Paul Dryden  
President  
ProMedic, LLC  
131 Bay Point Drive NE  
Saint Petersburg, Florida 33704

Re: K240561

Trade/Device Name: Rugged Oxygen Generator (ROG)  
Regulation Number: 21 CFR 868.5440  
Regulation Name: Portable oxygen generator  
Regulatory Class: Class II  
Product Code: CAW  
Dated: November 7, 2024  
Received: November 8, 2024

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](mailto: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 Anesthesia,  
Respiratory, and Sleep Devices  
OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT, and Dental Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K240561

Device Name

Rugged Oxygen Generator (ROG)

Indications for Use (Describe)

Intended to produce oxygen for emergency use at 6 LPM flow rate for at least 15 minutes (90 liters) for individuals 17 years and older requiring emergency or supplemental oxygen.

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

Page 1 of 4

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**Date Prepared:** December 4, 2024

**Sponsor:** Molecular Products Ltd.  
Parkway, Harlow Business Park, Harlow,  
Essex, CM19 5FR, UK

**Sponsor Contact:** Joe Atkinson – Technical Manager  
Phone - +44 (0)1279 401236

**Submission Correspondent:** Paul Dryden  
ProMedic, LLC

**Proprietary or Trade Name:** Rugged Oxygen Generator (ROG)  
**Common/Usual Name:** Oxygen Generator  
**Classification Name:** Generator, Oxygen, Portable  
**Product Code:** CAW  
**Regulation Number:** 21 CFR 868.5440

**Predicate Device:** ROGS – K131016  
**Proprietary or Trade Name:** Rugged Oxygen Generator (ROG)  
**Common/Usual Name:** Oxygen Generator  
**Classification Name:** Generator, Oxygen, Portable  
**Product Code:** CAW  
**Regulation Number:** 21 CFR 868.5440

### Device Description

The Rugged Oxygen Generator (ROG) is intended for environment such as emergency use, home use, and commercial use and is OTC. The ROG is designed to provide supplemental oxygen and is a single use product. The ROG is a chemical oxygen generator that produces a minimum of 90 liters of oxygen at  $\geq 96\%$  purity for minimum of 15 minutes with an average flow rate of 6 liters per minute or greater. There is a need for oxygen in a variety of applications/locations where compressed oxygen cylinders are not suitable.

### Principle of Operation

The subject device is initiated through a friction interaction between an integrated phosphorous match and the candle block. To initiate, open the lid and turn the dial clockwise 2-3 times. The turning of the dial will rotate the match and screw the match down into the candle block. This will start the chemical reaction, which will produce oxygen. Once oxygen is flowing, close the lid and place the face mask onto patient.

### Indications for Use:

Intended to produce oxygen for emergency use at 6 LPM flow rate for at least 15 minutes (90 liters) for individuals 17 years and older requiring emergency or supplemental oxygen.

### Patient Population:

For individuals 17 years and older requiring emergency or supplemental oxygen.

### Environments of use:

Emergency use, home use, and commercial use

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510(k) Summary

Page 2 of 4

	<b>Subject Device Molecular Products Rugged Oxygen Generator (ROG)</b>	<b>Predicate device Molecular Products ROG</b>	<b>Comparison</b>
<b>K#</b>	K240561	K131016	
<b>Product Code</b>	CAW	CAW	Identical
<b>CFR</b>	21 CFR 868.5440	21 CFR 868.5440	Identical
<b>Indications for Use</b>	Intended to produce oxygen for emergency use at 6 LPM flow rate for at least 15 minutes (90 liters) for individuals 17 years and older requiring emergency or supplemental oxygen	Intended to produce oxygen for emergency use at 6 LPM flow rate for at least 15 minutes (90 liters)	Similar Population was not specified
<b>Patient Population</b>	For individuals 17 years and older requiring emergency or supplemental oxygen.	Individuals requiring emergency or supplemental oxygen.	Similar Population was not specified
<b>Environment of Use</b>	Emergency, OTC, home and commercial settings	Emergency, OTC, home and commercial settings	Identical
<b>Contraindications</b>	Same	Same	Identical
<b>Method for oxygen generation</b>	Chemical reaction	Chemical reaction	Identical
<b>Patient Interface</b>	Standard oxygen mask	Standard oxygen mask or nasal Standard oxygen mask or nasal cannula	The subject device does not offer a nasal cannula for use, which does not raise different safety or efficacy as a mask is still available for use like the predicate.
<b>Specifications</b>	% Oxygen – 96% Flow rate minimum - 6 LPM Duration at least 15 minutes Initiation of oxygen flow – 5 seconds	% Oxygen - 99% Flow rate minimum - 6 LPM Duration at least 15 minutes Initiation of oxygen flow – 5 seconds	Oxygen purity is not a FDA guidance specification. USP defines medical oxygen purity as > 93%. This change in the specification does not Raise different risk concerns.
<b>Single Use, Disposable</b>	Yes	Yes	Identical
<b>OTC</b>	Yes	Yes	Identical
<b>VOC / PM Testing</b>	Yes	Yes	Identical
<b>Housing temperature</b>	<45°C Maximum	<45°C Maximum	Identical
<b>Temperature of gas at outlet</b>	<40°C Maximum	<40°C Maximum	Identical
<b>Storage temperatures</b>	0° to + 40°C / 32° to +1 04°F	0° to + 40°C / 32° to +1 04°F	Identical
<b>Dimensions</b>	28.5 cm x 11.5 cm	28.5 cm x 11.5 cm	Similar
<b>Gross weight</b>	1.5kg	1.5kg	Similar
<b>Accessories</b>	None – User supplied	Mask and oxygen cannula	Mask and tubing are user supplied

### **Substantial Equivalence Discussion**

The table above compares the key features of the proposed device with the identified predicate – ROG – K131016. The comparison demonstrates that the subject device can be found to be substantially equivalent to the predicate device.

#### **Indications for Use –**

The indications for use are similar for the subject device when compared to the predicate device.

**Discussion** – The indications for use are similar.

#### **Technology and construction –**

The technology and principle of operation is similar for the subject device when compared to the predicate device.

**Discussion** – Both the subject and predicate device have identical principles of Operation.

#### **Environment of Use –**

The environments of use are identical to predicate, which are Emergency, OTC, home and commercial settings.

**Discussion** – The environments of use are the identical.

#### **Patient Population –**

The patient population is similar for individuals requiring emergency oxygen.

**Discussion** – The subject and predicate device patient populations are similar.

### **Non-Clinical Testing Summary**

#### **Bench testing –**

Performance testing demonstrated that the subject device met its acceptance criteria.

Testing included:

- Casing, Gas at patient temperature testing
- Shock and Vibration
- Drop Testing
- Sand and Rain Blow Testing
- Flow Duration

**Discussion** – The test results are similar to the predicate and within pre-defined acceptance criteria.

#### **Biocompatibility –**

The sponsor performed ISO 18562-2 and ISO 18562-3 testing.

**Discussion** – The subject device was found to meet the applicable requirements for biocompatibility safety for the intended population

#### **Discussion of Differences**

The subject does not include oxygen tubing and mask as was included by the predicate device. The oxygen percent is 96% as compared to the predicate, which was 99%. The flow rate minimum, duration, and initiation of oxygen remain unchanged. The subject device also incorporates design updates from Molecular Product's own device – the predicate ROG – K131016.

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The changes incorporated in the subject device do not raise any new concerns of safety or effectiveness.

**Substantial Equivalence Conclusion**

Through testing outlined above, the sponsor has demonstrated that the subject device comparably performs to the predicate, and the subject device do not raise any new concerns of safety or effectiveness when compared to the predicate ROG – K131016.

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