

K240561 Rugged Oxygen Generator (ROG) (R001-00001)Dec 6, 2024
281 days to decisionK240561 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k240561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Feb 29, 2024
Decision date	Dec 6, 2024
Days to decision	281 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Molecular Products , Ltd.
Location	Thaxted, Essex, GB
Contact	Joe Atkinson
510(k) history	4 submissions · 4 cleared · 1992-2024

REGULATORY CONSULTANT

Consulting firm	ProMedic, LLC
Contact	Paul Dryden

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240561/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026