

K182454 O2 Concepts Oxlife Independence Model 301-0001Dec 20, 2018
104 days to decisionK182454 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k182454/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Sep 7, 2018
Decision date	Dec 20, 2018
Days to decision	104 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	O2 Concepts, LLC
Location	Middlebury, CT, US
Contact	Kathryn G. Forgione
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	MARK JOB

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

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