

**K162433 GCE Zen-O Portable Oxygen Concentrator**May 24, 2017  
266 days to decisionK162433 · Product code: **CAW** · Anesthesiology  
Source: <https://www.510kdatabase.net/k162433/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Aug 31, 2016
Decision date	May 24, 2017
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oxus, Inc.</b>
Location	Auburn Hills, MI, US
Contact	RYAN LENARCIC
510(k) history	2 submissions · 2 cleared · 2017-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162433/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026