

**K251764 Oxygen Concentrator-P2-O5E**Dec 22, 2025  
196 days to decisionK251764 · Product code: **CAW** · Anesthesiology  
Source: <https://www.510kdatabase.net/k251764/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Jun 9, 2025
Decision date	Dec 22, 2025
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Qingdao Kingon Medical Science and Technology Co., Ltd.</b>
Location	Qingdao Free Trade Zone, CN
Contact	Zhang Benrong
510(k) history	5 submissions · 5 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	DAVE YUNGVIRT

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251764/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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