

K210371 Portable Oxygen Concentrator, model: P2-E6Jun 3, 2022
480 days to decisionK210371 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k210371/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Feb 8, 2021
Decision date	Jun 3, 2022
Days to decision	480 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Qimmiq Medical Consulting Service Co., Ltd.
Contact	You Yijie

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

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