

K213210 Oxygen Concentrator, Model JAY-5AWDec 8, 2022
435 days to decisionK213210 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k213210/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Sep 29, 2021
Decision date	Dec 8, 2022
Days to decision	435 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Longfian Scitech Co., Ltd.
Location	Miami, FL, US
Contact	Shi Lei
510(k) history	3 submissions · 3 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	P&L Scientific, Inc.
Contact	Jun Peng

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

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