

K172234 Oxygen ConcentratorJun 1, 2018
311 days to decisionK172234 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k172234/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Jul 25, 2017
Decision date	Jun 1, 2018
Days to decision	311 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sysmed (China) Co., Ltd.
Location	Shenyang, CN
Contact	Jian Yue
510(k) history	2 submissions · 2 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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

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