

K203086 X-PLO2RMar 2, 2021
140 days to decisionK203086 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k203086/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Oct 13, 2020
Decision date	Mar 2, 2021
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Belluscura, LLC
Location	Plano, TX, US
Contact	Sarah Clark
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Regulatory Insight, Inc.
Contact	Kevin Walls

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

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