

K213948 OxyMinderMar 17, 2022
90 days to decisionK213948 · Product code: **CCL** · Anesthesiology
Source: <https://www.510kdatabase.net/k213948/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Oxygen, Gaseous-phase (CCL)
Date received	Dec 17, 2021
Decision date	Mar 17, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Med Devices, Inc.
Location	Mchenry, IL, US
Contact	Ken K Close
510(k) history	14 submissions · 13 cleared · 1980-2022

REGULATORY CONSULTANT

Consulting firm	ProMedic Consulting, LLC
Contact	Paul Dryden

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213948/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026