

K231288 VyvoMar 4, 2024
305 days to decisionK231288 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k231288/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	May 4, 2023
Decision date	Mar 4, 2024
Days to decision	305 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vyvo Technology Corp.(Vt)
Location	Miami, FL, US
Contact	Alfonso Cioffi
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Shenzhen Global Medical Technology Services Co., Ltd.
Contact	Aileen Fu

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/k231288/> 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 13, 2026