

K241418 OptoMonitor 3Feb 12, 2025
268 days to decisionK241418 · Product code: **DXO** · CardiovascularSource: <https://www.510kdatabase.net/k241418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	May 20, 2024
Decision date	Feb 12, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Opsens, Inc.
Location	Quebec, CA
Contact	Marc Chaunet
510(k) history	10 submissions · 10 cleared · 2015-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241418/> 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 14, 2026