FDA 510(k) Premarket Notification

K251367 OptoMonitor 3

CLEARED

Jan 16, 2026
260 days to decision

K251367 · Product code: **DXO** · Cardiovascular
Source: https://www.510kdatabase.net/k251367/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	May 1, 2025
Decision date	Jan 16, 2026
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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