FDA 510(k) Premarket Notification

K241418 OptoMonitor 3

CLEARED

Feb 12, 2025
268 days to decision

K241418 · Product code: **DXO** · Cardiovascular
Source: 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