

K202943 OptoMonitor 3Nov 24, 2020
55 days to decisionK202943 · Product code: **DXO** · Cardiovascular
Source: <https://www.510kdatabase.net/k202943/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	Sep 30, 2020
Decision date	Nov 24, 2020
Days to decision	55 days
Third-party review	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/k202943/> 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 25, 2026