

**K161263 OptoMonitor II**Sep 13, 2016  
131 days to decisionK161263 · Product code: **DXO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k161263/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	May 5, 2016
Decision date	Sep 13, 2016
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Opsens, Inc.</b>
Location	Quebec, CA
Contact	Vanessa Mootosamy
510(k) history	10 submissions · 10 cleared · 2015-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161263/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026