

**K152991 OptoWire Deux**Feb 11, 2016  
121 days to decisionK152991 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k152991/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Oct 13, 2015
Decision date	Feb 11, 2016
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Opsens</b>
Location	Quebec, CA
Contact	Vanessa Mootosamy
510(k) history	1 submissions · 1 cleared · 2016-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152991/> 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 June 3, 2026