

**K213854 SavvyWire**Sep 14, 2022  
278 days to decisionK213854 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k213854/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 10, 2021
Decision date	Sep 14, 2022
Days to decision	278 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ultra Life Science Solutions, Inc.</b>
Contact	Christina Henza

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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