

K191907 OptoWire IIIJan 2, 2020
170 days to decisionK191907 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k191907/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jul 16, 2019
Decision date	Jan 2, 2020
Days to decision	170 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

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