

K142598 Opto Wire and OptoMonitor SystemJun 12, 2015
270 days to decisionK142598 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k142598/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Sep 15, 2014
Decision date	Jun 12, 2015
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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