

K240864 PacePro WireMay 24, 2024
57 days to decisionK240864 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k240864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 28, 2024
Decision date	May 24, 2024
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240864/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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