

K252674 Solo Pace Fusion System (SOLOFUSE1)Jan 9, 2026
137 days to decisionK252674 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k252674/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 25, 2025
Decision date	Jan 9, 2026
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Solo Pace, Inc.
Location	Petaluma, CA, US
Contact	Matt Olson
510(k) history	2 submissions · 2 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	Gateway Medical Consulting Services, LLC
Contact	Nancy Frame

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

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