

K254137 InQwire Amplatz Guide WireMay 22, 2026
151 days to decisionK254137 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k254137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 22, 2025
Decision date	May 22, 2026
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Merit Medical Ireland, Ltd.
Location	South Jordan, UT, US
Contact	Brian Coughlan
510(k) history	5 submissions · 5 cleared · 2012-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k254137/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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