

K213834 Cardio Flow Peripheral Guide WireMar 18, 2022
99 days to decisionK213834 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k213834/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 9, 2021
Decision date	Mar 18, 2022
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardio Flow Inc.,
Location	Mahtomedi, MN, US
Contact	Michael J. Kallok
510(k) history	5 submissions · 5 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Quality & Regulatory Associates, LLC
Contact	Michael J Kallok

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

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