FDA 510(k) Premarket Notification

K213834 Cardio Flow Peripheral Guide Wire

CLEARED

Mar 18, 2022
99 days to decision

K213834 · 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