

K252859 ZEUS Platform (FG0501US)May 29, 2026
262 days to decisionK252859 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k252859/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Sep 9, 2025
Decision date	May 29, 2026
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	iRhythm Technologies, Inc.
Location	San Francisco, CA, US
Contact	Brittany Davis
510(k) history	18 submissions · 18 cleared · 2008-2026

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