

K202527 Zio ECG Utilization Software (ZEUS) SystemMay 21, 2021
262 days to decisionK202527 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k202527/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Sep 1, 2020
Decision date	May 21, 2021
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	Gabrielle Logan
510(k) history	17 submissions · 17 cleared · 2008-2025

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