

K222389 ZEUS SystemFeb 15, 2023
191 days to decisionK222389 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k222389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Aug 8, 2022
Decision date	Feb 15, 2023
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	iRhythm Technologies, Inc.
Location	San Francisco, CA, US
Contact	Vishal Kanani
510(k) history	17 submissions · 17 cleared · 2008-2025

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