

K213409 ZEUS System (Zio Watch)Jul 19, 2022
273 days to decisionK213409 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k213409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Oct 19, 2021
Decision date	Jul 19, 2022
Days to decision	273 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	Vishal Kanani
510(k) history	17 submissions · 17 cleared · 2008-2025

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