

K240029 Zio AT® device (A100A1001)Oct 21, 2024
291 days to decisionK240029 · Product code: **QYX** · Cardiovascular
Source: <https://www.510kdatabase.net/k240029/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Outpatient Cardiac Telemetry (QYX)
Date received	Jan 4, 2024
Decision date	Oct 21, 2024
Days to decision	291 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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