

**K163512 Zio AT ECG Monitoring System**Jun 2, 2017  
169 days to decisionK163512 · Product code: **QYX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k163512/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Outpatient Cardiac Telemetry (QYX)
Date received	Dec 15, 2016
Decision date	Jun 2, 2017
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>iRhythm Technologies, Inc.</b>
Location	San Francisco, CA, US
Contact	RICH LAGUNA
510(k) history	17 submissions · 17 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163512/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 1, 2026