

**K160064 MoMe Kardia Wireless Ambulatory ECG Monitoring and Detection System**Mar 11, 2016  
58 days to decisionK160064 · Product code: **QYX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k160064/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Outpatient Cardiac Telemetry (QYX)
Date received	Jan 13, 2016
Decision date	Mar 11, 2016
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Infobionic, Inc.</b>
Location	Lowell, MA, US
Contact	NANCY BRIEFS
510(k) history	5 submissions · 5 cleared · 2014-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160064/>; 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 May 25, 2026