

**K172801 ECG SENTINEL System**Oct 18, 2017  
30 days to decisionK172801 · Product code: **DXH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k172801/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Sep 18, 2017
Decision date	Oct 18, 2017
Days to decision	30 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardiomedix, Inc.</b>
Location	Evanston, IL, US
Contact	Zipora David
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172801/> 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 31, 2026