

**K171816 Kardia Band System**Nov 16, 2017  
150 days to decisionK171816 · Product code: **DXH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k171816/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Jun 19, 2017
Decision date	Nov 16, 2017
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>AliveCor, Inc.</b>
Location	San Francisco, CA, US
Contact	Prabhu Raghavan
510(k) history	19 submissions · 19 cleared · 2012-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171816/> 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 24, 2026