

**K231010 Corvair**Jun 7, 2024  
427 days to decisionK231010 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k231010/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 7, 2023
Decision date	Jun 7, 2024
Days to decision	427 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mdqr, LLC</b>
Contact	Prabhu Raghavan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231010/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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