

**K232035 Impala**Jun 7, 2024  
336 days to decisionK232035 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k232035/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jul 7, 2023
Decision date	Jun 7, 2024
Days to decision	336 days
Third-party review	No
Combination product	No
PCCP authorized	No
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](https://accessdata.fda.gov)

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