FDA 510(k) Premarket Notification

K232035 Impala

CLEARED

Jun 7, 2024
336 days to decision

K232035 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k232035/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Mdqr, LLC**
Contact	Prabhu Raghavan

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