FDA 510(k) Premarket Notification

K220350 KardiaMobile 6L

CLEARED

May 25, 2022
107 days to decision

K220350 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k220350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Feb 7, 2022
Decision date	May 25, 2022
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**AliveCor, Inc.**
Location	San Francisco, CA, US
Contact	Susan Noriega
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