FDA 510(k) Premarket Notification

K210753 KardiaMobile 6L

CLEARED

Jun 30, 2021
107 days to decision

K210753 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k210753/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Mar 15, 2021
Decision date	Jun 30, 2021
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	Saket Bhatt
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