FDA 510(k) Premarket Notification

# K212662 AliveCor QT Service

**CLEARED**

Apr 26, 2022
246 days to decision

K212662 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k212662/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Computer, Diagnostic, Programmable (DQK) |
| Date received | Aug 23, 2021 |
| Decision date | Apr 26, 2022 |
| Days to decision | 246 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