

K233253 eCARTv5 Clinical Deterioration Suite (“eCART”)Jun 21, 2024
267 days to decisionK233253 · Product code: **QNL** · Cardiovascular
Source: <https://www.510kdatabase.net/k233253/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medium-term Adjunctive Predictive Cardiovascular Indicator (QNL)
Date received	Sep 28, 2023
Decision date	Jun 21, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Agilemd, Inc.
Location	San Francisco, CA, US
Contact	Borna Safabakhsh
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Kelliann H. Payne

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233253/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026