FDA 510(k) Premarket Notification

CLEARED

K233253 eCARTv5 Clinical Deterioration Suite (“eCART”)

Jun 21, 2024
267 days to decision

K233253 · 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