

K221774 Garmin ECG AppJan 12, 2023
205 days to decisionK221774 · Product code: **QDA** · CardiovascularSource: <https://www.510kdatabase.net/k221774/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph Software For Over-the-counter Use (QDA)
Date received	Jun 21, 2022
Decision date	Jan 12, 2023
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Garmin International, Inc.
Location	Olathe, KS, US
Contact	Travis Johnson
510(k) history	1 submissions · 1 cleared · 2023-2023

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