

**K240909 Samsung ECG App v 1.3 (ECG)**Aug 2, 2024  
122 days to decisionK240909 · Product code: **QDA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k240909/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph Software For Over-the-counter Use (QDA)
Date received	Apr 2, 2024
Decision date	Aug 2, 2024
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Samsung Electronics Co., Ltd.</b>
Location	Echo, OR, US
Contact	Hon Pak
Website	<a href="http://www.samsung.com">http://www.samsung.com</a>
510(k) history	40 submissions · 39 cleared · 2013-2024

Samsung Electronics Co., Ltd. is a South Korean multinational electronics corporation headquartered in Suwon. The company maintains a regulatory presence in the United States through its Echo, US location. Samsung has submitted total applications for FDA 510(k) clearance and received clearances. The company's regulatory focus centers on Radiology devices, which represent 83% of submissions. Samsung's FDA 510(k) clearance history spans from 2013 to 2024, with recent clearances demonstrating continued regulatory activity in medical imaging and cardiovascular monitoring tech...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Samsung Research America, Inc.</b>
Contact	Matthew Wiggins

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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