

K251670 MAC 7 Resting ECG Analysis SystemJan 26, 2026
241 days to decisionK251670 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k251670/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	May 30, 2025
Decision date	Jan 26, 2026
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Systems Information Technologies, Inc.
Location	Milwaukee, WI, US
Contact	Yang Honghong
510(k) history	31 submissions · 31 cleared · 2010-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251670/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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