

K221321 MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System

Oct 18, 2022
165 days to decision

K221321 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k221321/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	May 6, 2022
Decision date	Oct 18, 2022
Days to decision	165 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	Honghong Yang
510(k) history	31 submissions · 31 cleared · 2010-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k221321/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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