

K221904 EK12 V2 AlgorithmDec 20, 2022
173 days to decisionK221904 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k221904/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jun 30, 2022
Decision date	Dec 20, 2022
Days to decision	173 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	Shlomi Deler
510(k) history	31 submissions · 31 cleared · 2010-2026

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