

K141963 12SL ECG ANALYSIS PROGRAMFeb 5, 2015
202 days to decisionK141963 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k141963/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 18, 2014
Decision date	Feb 5, 2015
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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