FDA 510(k) Premarket Notification

K092369 12SL ECG ANALYSIS PROGRAM

CLEARED

Feb 24, 2010
203 days to decision

K092369 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k092369/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Aug 5, 2009
Decision date	Feb 24, 2010
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Medical Systems Information Technologies**
Location	Mchenry, IL, US
Contact	JOE LUCAS
510(k) history	136 submissions · 132 cleared · 1978-2012