

K014213 SIEMENS INFINITY GATEWAY SUITEJan 17, 2002
27 days to decisionK014213 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k014213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Dec 21, 2001
Decision date	Jan 17, 2002
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Medical Solutions USA, Inc.
Location	Hoffman Estates, IL, US
Contact	PENELOPE H GRECO
510(k) history	778 submissions · 778 cleared · 1980-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k014213/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 15, 2026