FDA 510(k) Premarket Notification

CLEARED

K030657 SIEMENS INFINITY GATEWAY SUITE, MODEL VF2

Mar 21, 2003
18 days to decision

K030657 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k030657/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Mar 3, 2003
Decision date	Mar 21, 2003
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medical Solutions**
Location	Danvers, MA, US
Contact	PENELOPE H GRECO
510(k) history	15 submissions · 15 cleared · 2003-2025