FDA 510(k) Premarket Notification

K030575 MODIFICATION TO SOLAR 9500 INFORMATION MONITOR

CLEARED

Mar 21, 2003
25 days to decision

K030575 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k030575/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Feb 24, 2003
Decision date	Mar 21, 2003
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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