FDA 510(k) Premarket Notification

K021435 DINAMAP PRO SERIES MONITOR, MODELS 110N,210N,310N,410N

CLEARED

May 22, 2002
16 days to decision

K021435 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k021435/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	May 6, 2002
Decision date	May 22, 2002
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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