FDA 510(k) Premarket Notification

CLEARED

K031376 DINAMAP PRO 1000 V3 MONITOR, MODEL 1100 SERIES

Jul 16, 2003
76 days to decision

K031376 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k031376/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	May 1, 2003
Decision date	Jul 16, 2003
Days to decision	76 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