FDA 510(k) Premarket Notification

K020290 DASH 3000/4000 PATIENT MONITOR

CLEARED

Aug 14, 2002
198 days to decision

K020290 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k020290/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jan 28, 2002
Decision date	Aug 14, 2002
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**General Electric Medical Systems Information Techn**
Location	Sugarland, TX, US
Contact	KAREN WEBB
510(k) history	33 submissions · 33 cleared · 1999-2002