FDA 510(k) Premarket Notification

CLEARED

K071073 SOLAR 8000 AND TRANSPORT PRO WITH PATIENT DATA MODULE

May 11, 2007
25 days to decision

K071073 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k071073/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 16, 2007
Decision date	May 11, 2007
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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