FDA 510(k) Premarket Notification

K131223 CARESCAPE MONITOR B650

CLEARED

Aug 28, 2013
120 days to decision

K131223 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k131223/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 30, 2013
Decision date	Aug 28, 2013
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**GE Healthcare Finland Oy**
Location	Madison, WI, US
Contact	JOEL KENT
510(k) history	30 submissions · 30 cleared · 2007-2023