FDA 510(k) Premarket Notification

K102239 CARESCAPE MONITOR B650

CLEARED

Oct 18, 2010
70 days to decision

K102239 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k102239/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Aug 9, 2010
Decision date	Oct 18, 2010
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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