

K132533 CARESCAPE MONITOR B450Dec 4, 2013
114 days to decisionK132533 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k132533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Aug 12, 2013
Decision date	Dec 4, 2013
Days to decision	114 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

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