

**K131223 CARESCAPE MONITOR B650**Aug 28, 2013  
120 days to decisionK131223 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k131223/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131223/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 24, 2026