

**K102239 CARESCAPE MONITOR B650**Oct 18, 2010  
70 days to decisionK102239 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k102239/>**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	Aug 9, 2010
Decision date	Oct 18, 2010
Days to decision	70 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	PAIVI ROIHA
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/k102239/> 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