

**K191323 Carescape B850**Jan 29, 2020  
259 days to decisionK191323 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k191323/>**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	May 15, 2019
Decision date	Jan 29, 2020
Days to decision	259 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/k191323/> 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 14, 2026