

**K213181 CARESCAPE B650, E-musb**Apr 13, 2022  
196 days to decisionK213181 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k213181/>**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	Sep 29, 2021
Decision date	Apr 13, 2022
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	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/k213181/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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