

K213363 CARESCAPE B450, E-musbApr 13, 2022
183 days to decisionK213363 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k213363/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Oct 12, 2021
Decision date	Apr 13, 2022
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	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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