

K191149 CARESCAPE B650Jan 21, 2020
266 days to decisionK191149 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k191149/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 30, 2019
Decision date	Jan 21, 2020
Days to decision	266 days
Third-party review	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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