

K191249 CARESCAPE B450Jan 24, 2020
260 days to decisionK191249 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k191249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	May 9, 2019
Decision date	Jan 24, 2020
Days to decision	260 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191249/> Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026