FDA 510(k) Premarket Notification

K191249 CARESCAPE B450

CLEARED

Jan 24, 2020
260 days to decision

K191249 · 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