FDA 510(k) Premarket Notification

K191323 Carescape B850

CLEARED

Jan 29, 2020
259 days to decision

K191323 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k191323/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	May 15, 2019
Decision date	Jan 29, 2020
Days to decision	259 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