FDA 510(k) Premarket Notification

K213336 Carescape B850, E-musb

CLEARED

Apr 13, 2022
189 days to decision

K213336 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k213336/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Oct 6, 2021
Decision date	Apr 13, 2022
Days to decision	189 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