

K213234 CARESCAPE ONE and CARESCAPE DOCK F0, Model Numbers MBZ323 and MFA101, CARESCAPE ECG, Model Number MKE101, CARESCAPE TEMP, Model Number MKT101, CARESCAPE PRES, Model Number MKP101, CARESCAPE SPO2, Model Numbers MKS101 and MKS201Apr 12, 2022
194 days to decisionK213234 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k213234/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Sep 30, 2021
Decision date	Apr 12, 2022
Days to decision	194 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Systems Information Technologies, Inc.
Location	Milwaukee, WI, US
Contact	Joel Kent
510(k) history	31 submissions · 31 cleared · 2010-2026

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