

K201941 Monitor B125, Monitor B105Nov 4, 2020
114 days to decisionK201941 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k201941/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 13, 2020
Decision date	Nov 4, 2020
Days to decision	114 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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