

**K213490 Monitor B105M, Monitor B125M, Monitor B155M,
Monitor B105P, Monitor B125P**Apr 1, 2022
151 days to decisionK213490 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k213490/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 1, 2021
Decision date	Apr 1, 2022
Days to decision	151 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213490/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026