

K242562 Monitor B105MJul 9, 2025
315 days to decisionK242562 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k242562/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Aug 28, 2024
Decision date	Jul 9, 2025
Days to decision	315 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Monitor B125M; Monitor B155M; Monitor B105P; Monitor B125P

APPLICANT

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

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