K213490 Monitor B105M, Monitor B125M, Monitor B155M, Monitor B105P, Monitor B125P

CLEARED

Apr 1, 2022
151 days to decision

K213490 · 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