FDA 510(k) Premarket Notification

K233810 Portrait VSM

CLEARED

Apr 25, 2024
147 days to decision

K233810 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k233810/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Nov 30, 2023
Decision date	Apr 25, 2024
Days to decision	147 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	Jung William
510(k) history	31 submissions · 31 cleared · 2010-2026