

K234130 Portrait™ Mobile Monitoring Solution consists of: • Portrait™ Central Viewer Application (Portrait CVAXB) • Portrait™ Core Services (Portrait CSSXB) • Portrait™ Clinical Alarming Unit (Portrait CAU01) • Portrait™ Mobile Patient Monitor Hardware (Portrait HUBXB) • Portrait™ Mobile Patient Monitor Software (Portrait HSWXB) • Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SA01) • Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SP01) • Portrait™ Wearable Pulse O

Mar 20, 2024
83 days to decision

K234130 · Product code: MWI · Anesthesiology
Source: <https://www.510kdatabase.net/k234130/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Dec 28, 2023
Decision date	Mar 20, 2024
Days to decision	83 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
