

K243146 iCare APPFeb 3, 2025
126 days to decisionK243146 · Product code: **MWI** · CardiovascularSource: <https://www.510kdatabase.net/k243146/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 30, 2024
Decision date	Feb 3, 2025
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ihealth Labs, Inc.
Location	Sunnyvale, CA, US
Contact	Tianyang Liu
510(k) history	4 submissions · 4 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243146/> 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 13, 2026