FDA 510(k) Premarket Notification

K243146 iCare APP

CLEARED

Feb 3, 2025
126 days to decision

K243146 · Product code: **MWI** · Cardiovascular
Source: 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