FDA 510(k) Premarket Notification

CLEARED

K233038 Vital Signs monitor, Model: iM3s, iM3As, iM3Bs, iHM3s

Mar 8, 2024
165 days to decision

K233038 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k233038/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 25, 2023
Decision date	Mar 8, 2024
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Edan Instruments, Inc.**
Location	Shenzhen, CN
Contact	Tracy Yue
Website	https://www.edan.com.cn
510(k) history	92 submissions · 92 cleared · 2004-2026