

K202892 Vital Signs Monitor:iM3s, iM3As, iM3Bs, iHM3sJan 28, 2021
122 days to decisionK202892 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k202892/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 28, 2020
Decision date	Jan 28, 2021
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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