

K232962 Patient Monitor (iX10, iX12, iX15)Apr 19, 2024
211 days to decisionK232962 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k232962/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Sep 21, 2023
Decision date	Apr 19, 2024
Days to decision	211 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

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