

K250179 Patient Monitor (CX10, CX12, CX15, UX10, UX12, UX15)Jul 29, 2025
188 days to decisionK250179 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k250179/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jan 22, 2025
Decision date	Jul 29, 2025
Days to decision	188 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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