

K240320 Patient Monitor (RespArray)Jun 28, 2024
147 days to decisionK240320 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k240320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Feb 2, 2024
Decision date	Jun 28, 2024
Days to decision	147 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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