

K110922 PATIENT MONITORJul 20, 2011
110 days to decisionK110922 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k110922/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 1, 2011
Decision date	Jul 20, 2011
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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