

K113653 PATIENT MONITORFeb 6, 2012
56 days to decisionK113653 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k113653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Dec 12, 2011
Decision date	Feb 6, 2012
Days to decision	56 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113653/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 15, 2026