

K160981 Patient MonitorDec 22, 2016
259 days to decisionK160981 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k160981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 7, 2016
Decision date	Dec 22, 2016
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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