

K131971 IM60/IM70 PATIENT MONITORMar 20, 2014
265 days to decisionK131971 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k131971/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jun 28, 2013
Decision date	Mar 20, 2014
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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