FDA 510(k) Premarket Notification

K113623 PATIENT MONITOR

CLEARED

Feb 1, 2012
58 days to decision

K113623 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k113623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Dec 5, 2011
Decision date	Feb 1, 2012
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Edan Instruments, Inc.**
Location	Shenzhen, CN
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510(k) history	92 submissions · 92 cleared · 2004-2026