FDA 510(k) Premarket Notification

K152552 Patient Monitor

CLEARED

Apr 29, 2016
234 days to decision

K152552 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k152552/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Sep 8, 2015
Decision date	Apr 29, 2016
Days to decision	234 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