FDA 510(k) Premarket Notification

K202336 Patient Monitor

CLEARED

Jan 23, 2021
159 days to decision

K202336 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k202336/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Aug 17, 2020
Decision date	Jan 23, 2021
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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