FDA 510(k) Premarket Notification

CLEARED

K220308 Patient Monitor: RespArray

Aug 11, 2022
190 days to decision

K220308 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k220308/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Feb 2, 2022
Decision date	Aug 11, 2022
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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