FDA 510(k) Premarket Notification

K192514 Patient Monitor

CLEARED

Apr 2, 2020
203 days to decision

K192514 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k192514/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Sep 12, 2019
Decision date	Apr 2, 2020
Days to decision	203 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