

**K192514 Patient Monitor**Apr 2, 2020  
203 days to decisionK192514 · 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	<b>Edan Instruments, Inc.</b>
Location	Shenzhen, CN
Contact	Alice Yang
Website	<a href="https://www.edan.com.cn">https://www.edan.com.cn</a>
510(k) history	92 submissions · 92 cleared · 2004-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192514/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026