

K202336 Patient MonitorJan 23, 2021
159 days to decisionK202336 · 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202336/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026