

K143372 AWAREApr 2, 2015
128 days to decisionK143372 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k143372/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI) |
| Date received | Nov 25, 2014 |
| Decision date | Apr 2, 2015 |
| Days to decision | 128 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ambient Clinical Analytics |
| Location | Rochester, NY, US |
| Contact | ALLEN BERNING |
| 510(k) history | 1 submissions · 1 cleared · 2015-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143372/> 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 June 4, 2026