

**K142424 DR300 HOLTER MONITOR**Nov 25, 2014  
88 days to decisionK142424 · Product code: **MWJ** · CardiovascularSource: <https://www.510kdatabase.net/k142424/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                      |
| Submission type       | Traditional   |
| Device classification | Electrocardiograph, Ambulatory (without Analysis) (MWJ) |
| Date received         | Aug 29, 2014  |
| Decision date         | Nov 25, 2014  |
| Days to decision      | 88 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>North East Monitoring, Inc.</b>      |
| Location       | Sudbury, MA, US                         |
| Contact        | SHERRY STEELE                           |
| 510(k) history | 10 submissions · 10 cleared · 1995-2014 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142424/> 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 May 24, 2026