

**K043010 HOLTER RECORDER H3+**Feb 25, 2005  
116 days to decisionK043010 · Product code: **MWJ** · CardiovascularSource: <https://www.510kdatabase.net/k043010/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                      |
| Submission type       | Abbreviated   |
| Device classification | Electrocardiograph, Ambulatory (without Analysis) (MWJ) |
| Date received         | Nov 1, 2004   |
| Decision date         | Feb 25, 2005  |
| Days to decision      | 116 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Mortara Instrument, Inc.</b>         |
| Location       | Walker, MI, US                          |
| Contact        | HARLAN L VAN MATRE                      |
| 510(k) history | 51 submissions · 51 cleared · 1983-2019 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043010/> 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 19, 2026