

**K092663 ELI 350 ELECTROCARDIOGRAPH**Dec 14, 2009  
105 days to decisionK092663 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k092663/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Abbreviated                        |
| Device classification | Electrocardiograph (DPS)           |
| Date received         | Aug 31, 2009                       |
| Decision date         | Dec 14, 2009                       |
| Days to decision      | 105 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092663/> 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