

**K944262 ECG MONITOR**May 12, 1995  
255 days to decisionK944262 · Product code: **DRT** · CardiovascularSource: <https://www.510kdatabase.net/k944262/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                           |
| Submission type       | Traditional  |
| Device classification | Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT) |
| Date received         | Aug 30, 1994   |
| Decision date         | May 12, 1995   |
| Days to decision      | 255 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Fukuda Denshi USA, Inc.</b>          |
| Location       | Mchenry, IL, US                         |
| Contact        | SUSAN D GOLDSTEIN-FALF                  |
| 510(k) history | 68 submissions · 68 cleared · 1984-2018 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944262/> 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 18, 2026