

**K941965 EZ-RANGE**Apr 25, 1995  
368 days to decisionK941965 · Product code: **JPK** · Hematology  
Source: <https://www.510kdatabase.net/k941965/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Mixture, Hematology Quality Control (JPK) |
| Date received         | Apr 22, 1994                              |
| Decision date         | Apr 25, 1995                              |
| Days to decision      | 368 days                                  |
| Third-party review    | No  |
| Summary / Statement   | Statement                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Hematronix, Inc.</b>               |
| Location       | Plano, TX, US                         |
| Contact        | DEBBY BERCE                           |
| 510(k) history | 9 submissions · 9 cleared · 1990-2001 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k941965/> 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 28, 2026