

**K843577 ULTRAXLONE ECL-01-1000 CELL LINE**Oct 31, 1984  
50 days to decisionK843577 · Product code: **KIR** · Hematology  
Source: <https://www.510kdatabase.net/k843577/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Cells, Animal And Human, Cultured (KIR) |
| Date received         | Sep 11, 1984                            |
| Decision date         | Oct 31, 1984                            |
| Days to decision      | 50 days                                 |
| Third-party review    | No                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Earl-Clay Laboratories, Inc.</b>     |
| Location       | Mchenry, IL, US                         |
| Contact        | ROBERT E LOVINS                         |
| 510(k) history | 21 submissions · 21 cleared · 1984-1986 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k843577/>, 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 14, 2026