

**K853391 MULTIPURPOSE IMMUNOCHEMISTRY SYS-LA-2000**Oct 1, 1985  
49 days to decisionK853391 · Product code: **JJE** · Chemistry  
Source: <https://www.510kdatabase.net/k853391/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                  |
| Submission type       | Traditional   |
| Device classification | Analyzer, Chemistry (photometric, Discrete), For Clinical Use (JJE) |
| Date received         | Aug 13, 1985  |
| Decision date         | Oct 1, 1985   |
| Days to decision      | 49 days   |
| Third-party review    | No  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Eiken Chemical Co., Inc.</b>       |
| Location       | Venice, CA, US                        |
| Contact        | JAMES F GODFREY                       |
| 510(k) history | 2 submissions · 2 cleared · 1985-1986 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853391/>; 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 30, 2026