

**K951133 CEDIA DAU PROPOXYPHENE ASSAY**May 2, 1995  
50 days to decisionK951133 · Product code: **JXN** · Toxicology  
Source: <https://www.510kdatabase.net/k951133/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Enzyme Immunoassay, Propoxyphene (JXN) |
| Date received         | Mar 13, 1995                           |
| Decision date         | May 2, 1995                            |
| Days to decision      | 50 days                                |
| Third-party review    | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---|
| Company        | <b>Microgenics Corp.</b>                  |
| Location       | Concord, CA, US                           |
| Contact        | MARY KONING                               |
| 510(k) history | 107 submissions · 106 cleared · 1985-2013 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k951133/> 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