

**K041102 IMMULISA ANTINUCLEAR ANTIBODY SCREEN ELISA**Oct 26, 2004  
182 days to decisionK041102 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k041102/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                             |
| Submission type       | Traditional  |
| Device classification | Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM) |
| Date received         | Apr 27, 2004   |
| Decision date         | Oct 26, 2004   |
| Days to decision      | 182 days   |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Immco Diagnostics, Inc.</b>          |
| Location       | Buffalo, NY, US                         |
| Contact        | KEVIN J LAWSON                          |
| 510(k) history | 55 submissions · 55 cleared · 1988-2018 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041102/> 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 30, 2026