

**K151559 ImmuLisa Enhanced Centromere Antibody ELISA**Mar 11, 2016  
275 days to decisionK151559 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k151559/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Jun 10, 2015
Decision date	Mar 11, 2016
Days to decision	275 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Immco Diagnostics, Inc.</b>
Location	Buffalo, NY, US
Contact	KEVIN 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/k151559/> 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