

**K113143 IMMULISA SCI-70 ANTIBODY ELISA**Dec 2, 2011  
38 days to decisionK113143 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k113143/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Oct 25, 2011
Decision date	Dec 2, 2011
Days to decision	38 days
Third-party review	Yes
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/k113143/> 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