

**K142781 ImmuLisa Enhanced SS-A (Ro) Antibody ELISA, ImmuLisa Enhanced SS-B (La) Antibody ELISA, ImmuLisa Enhanced Sm Antibody ELISA, ImmuLisa Enhanced RNP Antibody ELISA**Mar 31, 2015  
186 days to decisionK142781 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k142781/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Sep 26, 2014
Decision date	Mar 31, 2015
Days to decision	186 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 Lawson
510(k) history	55 submissions · 55 cleared · 1988-2018

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