

**K101319 IMMULISA DSDNA ANTIBODY ELISA**Dec 9, 2010  
212 days to decisionK101319 · Product code: **LRM** · Immunology  
Source: <https://www.510kdatabase.net/k101319/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM)
Date received	May 11, 2010
Decision date	Dec 9, 2010
Days to decision	212 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 LAWSON
510(k) history	55 submissions · 55 cleared · 1988-2018

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