

**K143736 ImmuLisa Enhanced RF IgA Antibody ELISA,
ImmuLisa Enhanced RF IgG Antibody ELISA, ImmuLisa
Enhanced RF IgM Antibody ELISA, ImmuLisa Enhanced RF
Antibody Screen ELISA**Sep 23, 2015
267 days to decisionK143736 · Product code: DHR · Immunology
Source: <https://www.510kdatabase.net/k143736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Dec 30, 2014
Decision date	Sep 23, 2015
Days to decision	267 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Immco Diagnostics, Inc.
Location	Buffalo, NY, US
Contact	Kevin Lawson
510(k) history	55 submissions · 55 cleared · 1988-2018

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