

K163133 ImmuLisa Enhanced AMA IgG Antibody ELISAAug 8, 2017
273 days to decisionK163133 · Product code: **DBM** · Immunology
Source: <https://www.510kdatabase.net/k163133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM)
Date received	Nov 8, 2016
Decision date	Aug 8, 2017
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary
Other names	ImmuLisa Enhanced AMA IgA/IgG/IgM Antibody ELISA

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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