

**K163177 ImmuLisa Enhanced Gliadin IgA Antibody ELISA,  
ImmuLisa Enhanced Gliadin IgG Antibody ELISA**Jul 28, 2017  
256 days to decisionK163177 · Product code: **MST** · Immunology  
Source: <https://www.510kdatabase.net/k163177/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Gliadin (MST)
Date received	Nov 14, 2016
Decision date	Jul 28, 2017
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

**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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163177/>. 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