

**K123713 IMMULISA ENHANCED CELIAC FUSION (TTG/DGP)
IGA/IGG ANTIBODY ELISA**Oct 25, 2013
325 days to decisionK123713 · Product code: **MVM** · Immunology
Source: <https://www.510kdatabase.net/k123713/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Dec 4, 2012
Decision date	Oct 25, 2013
Days to decision	325 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123713/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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