

K162788 ImmuLisa Enhanced B2GP1 IgA Antibody ELISA, ImmuLisa Enhanced B2GP1 IgG Antibody ELISA, ImmuLisa Enhanced B2GP1 IgM Antibody ELISA, ImmuLisa Enhanced B2GP1 IgA/IgG/IgM Antibody ELISAJun 19, 2017
259 days to decisionK162788 · Product code: **MSV** · Immunology
Source: <https://www.510kdatabase.net/k162788/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System,test,antibodies,b2 - Glycoprotein I (b2 - Gpi) (MSV)
Date received	Oct 3, 2016
Decision date	Jun 19, 2017
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

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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