

**K112414 ELIA B2-GLYCOPROTEIN I IGA IMMUNOASSAY**Jun 22, 2012  
305 days to decisionK112414 · Product code: **MSV** · Immunology  
Source: <https://www.510kdatabase.net/k112414/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System,test,antibodies,b2 - Glycoprotein I (b2 - Gpi) (MSV)
Date received	Aug 22, 2011
Decision date	Jun 22, 2012
Days to decision	305 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Phadia US, Inc.</b>
Location	Portae, MI, US
Contact	MARTIN ROBERT MANN
510(k) history	22 submissions · 21 cleared · 2006-2015

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