

**K100588 HUMAN IGA2 KIT FOR USE ON THE SPAPLUS**Aug 16, 2010  
167 days to decisionK100588 · Product code: **CFN** · Immunology  
Source: <https://www.510kdatabase.net/k100588/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Mar 2, 2010
Decision date	Aug 16, 2010
Days to decision	167 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>The Binding Site Group , Ltd.</b>
Location	Los Angeles, CA, US
Contact	JAY GELLER
Website	<a href="http://www.bindingsite.com/">http://www.bindingsite.com/</a>
510(k) history	43 submissions · 43 cleared · 2010-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100588/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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