

**K092450 HUMAN IGD KIT FOR USE ON SPAPLUS**Dec 28, 2009  
140 days to decisionK092450 · Product code: **CZJ** · Immunology  
Source: <https://www.510kdatabase.net/k092450/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igd, Antigen, Antiserum, Control (CZJ)
Date received	Aug 10, 2009
Decision date	Dec 28, 2009
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>The Binding Site</b>
Location	Santa Monica, CA, US
Contact	JAY GELLER
510(k) history	10 submissions · 10 cleared · 2004-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092450/> 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 June 7, 2026