

**K082823 HEVYLITE HUMAN IGA KAPPA AND IGA LAMBDA BN KITS**Mar 1, 2010  
522 days to decisionK082823 · Product code: **CFN** · Immunology  
Source: <https://www.510kdatabase.net/k082823/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Sep 25, 2008
Decision date	Mar 1, 2010
Days to decision	522 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 H 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/k082823/> 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 21, 2026