

**K113823 HEVYLITE HUMAN IGM KAPPA AND HEVYLITE IGM LAMBDA KIT**Mar 27, 2013  
456 days to decisionK113823 · Product code: **CFN** · Immunology  
Source: <https://www.510kdatabase.net/k113823/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Method, Nephelometric, Immunoglobulins (g, A, M) (CFN) |
| Date received         | Dec 27, 2011   |
| Decision date         | Mar 27, 2013   |
| Days to decision      | 456 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        | JILL CONSTANTINE  |
| 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/k113823/> Data sourced from FDA 510(k) public records (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 9, 2026