

**K132555 HEVYLITE HUMAN IGG KAPPA KIT AND HEVYLITE  
HUMAN IGG LAMBDA KIT**Dec 20, 2013  
128 days to decisionK132555 · Product code: **PCN** · Immunology  
Source: <https://www.510kdatabase.net/k132555/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoglobulin G Kappa Heavy And Light Chain Combined (PCN)
Date received	Aug 14, 2013
Decision date	Dec 20, 2013
Days to decision	128 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	Paul Kenny
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/k132555/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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