

**K152389 Optilite Hevylite IgM Kappa Kit**Dec 18, 2015  
116 days to decisionK152389 · Product code: **PDE** · Immunology  
Source: <https://www.510kdatabase.net/k152389/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoglobulin M Kappa Heavy And Light Chain Combined (PDE)
Date received	Aug 24, 2015
Decision date	Dec 18, 2015
Days to decision	116 days
Third-party review	No
Summary / Statement	Statement
Other names	Optilite Hevylite IgM Lambda Kit

**APPLICANT**

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Company	<b>The Binding Site Group , Ltd.</b>
Location	Los Angeles, CA, US
Contact	STEPHANIE THOULESS
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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