

**K150412 Optilite CH50 Reagent, Optilite CH50 Controls and Optilite CH50 Calibrator**Aug 28, 2015  
191 days to decisionK150412 · Product code: **DAE** · Immunology  
Source: <https://www.510kdatabase.net/k150412/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C9, Antigen, Antiserum, Control (DAE)
Date received	Feb 18, 2015
Decision date	Aug 28, 2015
Days to decision	191 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	Marianne Sender
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/k150412/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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