

**K151759 Hevylite Human IgA Kappa Kit for use on SPAPLUS,
Hevylite Human IgA Lambda Kit for use on SPAPLUS**Nov 6, 2015
130 days to decisionK151759 · Product code: **OPX** · Immunology
Source: <https://www.510kdatabase.net/k151759/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoglobulin A Kappa Heavy & Light Chain Combined (OPX)
Date received	Jun 29, 2015
Decision date	Nov 6, 2015
Days to decision	130 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	The Binding Site Group , Ltd.
Location	Los Angeles, CA, US
Contact	STEPHANIE THOULESS
Website	http://www.bindingsite.com/
510(k) history	43 submissions · 43 cleared · 2010-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151759/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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