

**K140105 HEVYLITE HUMAN IGA KAPPA KIT FOR USE ON
SIEMENS BNII, HEVYLITE HUMAN IGA LAMBDA KIT FOR USE
ON SIEMENS BNII**Mar 18, 2014
62 days to decisionK140105 · Product code: **OPX** · Immunology
Source: <https://www.510kdatabase.net/k140105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoglobulin A Kappa Heavy & Light Chain Combined (OPX)
Date received	Jan 15, 2014
Decision date	Mar 18, 2014
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	The Binding Site
Location	Santa Monica, CA, US
Contact	Paul Kenny
510(k) history	10 submissions · 10 cleared · 2004-2014

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