

K161854 Hevylite Human IgG Kappa Kit for use on the SPAPLUS, Hevylite Human IgG Lambda Kit for use on the SPAPLUS

Oct 4, 2016
90 days to decision

K161854 · Product code: **PCN** · Immunology
Source: <https://www.510kdatabase.net/k161854/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoglobulin G Kappa Heavy And Light Chain Combined (PCN)
Date received	Jul 6, 2016
Decision date	Oct 4, 2016
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161854/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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