

**K140686 HEVYLITE HUMAN IGM KAPPA AND LAMBDA KIT
FOR USE ON SPAPLUS**Aug 6, 2014
140 days to decisionK140686 · Product code: **PDE** · Immunology
Source: <https://www.510kdatabase.net/k140686/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoglobulin M Kappa Heavy And Light Chain Combined (PDE)
Date received	Mar 19, 2014
Decision date	Aug 6, 2014
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140686/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 6, 2026