

K160819 Optilite Hevylite IgA Kappa Kit, Optilite Hevylite IgA Lambda KitJun 16, 2016
84 days to decisionK160819 · Product code: **OPX** · Immunology
Source: <https://www.510kdatabase.net/k160819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoglobulin A Kappa Heavy & Light Chain Combined (OPX)
Date received	Mar 24, 2016
Decision date	Jun 16, 2016
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160819/> 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 2, 2026