

**K231290 Optilite® Freelite® Kappa Free Kit, Optilite® Freelite®
Lambda Free Kit**Jan 24, 2024
265 days to decisionK231290 · Product code: **DFH** · Immunology
Source: <https://www.510kdatabase.net/k231290/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	May 4, 2023
Decision date	Jan 24, 2024
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	The Binding Site, Ltd.
Location	Los Angeles, CA, US
Contact	Jolanta Wolff
510(k) history	115 submissions · 115 cleared · 1988-2024

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