

K250549 Optilite® Freelite Mx Kappa Free KitMay 23, 2025
87 days to decisionK250549 · Product code: **DFH** · Immunology
Source: <https://www.510kdatabase.net/k250549/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Feb 25, 2025
Decision date	May 23, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Optilite® Freelite Mx Lambda Free Kit

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250549/> 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 May 13, 2026