

**K051915 FREELITE HUMAN KAPPA AND LAMBDA FREE KITS
FOR USE ON THE BAYER ADVIA 1650 ANALYZER**

Sep 6, 2005
53 days to decision

K051915 · Product code: **DFH** · Immunology
Source: <https://www.510kdatabase.net/k051915/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Jul 15, 2005
Decision date	Sep 6, 2005
Days to decision	53 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k051915/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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