

K003669 KAPPA IMAGE FREELITE KITFeb 1, 2001
65 days to decisionK003669 · Product code: **DFH** · Immunology
Source: <https://www.510kdatabase.net/k003669/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Nov 28, 2000
Decision date	Feb 1, 2001
Days to decision	65 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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