

K010441 FREELITE KAPPA FREE KITApr 26, 2001
72 days to decisionK010441 · Product code: **DEH** · Immunology
Source: <https://www.510kdatabase.net/k010441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lambda, Antigen, Antiserum, Control (DEH)
Date received	Feb 13, 2001
Decision date	Apr 26, 2001
Days to decision	72 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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