

**K033811 FREELITE HUMAN KAPPA AND LAMBDA FREE KITS
FOR USE ON THE OLYMPUS AU ANALYZER**Jan 30, 2004
52 days to decisionK033811 · Product code: **DEH** · Immunology
Source: <https://www.510kdatabase.net/k033811/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lambda, Antigen, Antiserum, Control (DEH)
Date received	Dec 9, 2003
Decision date	Jan 30, 2004
Days to decision	52 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033811/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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