

K023131 FREELITE HUMAN LAMBDA FREE KITJan 21, 2003
134 days to decisionK023131 · Product code: **DEH** · Immunology
Source: <https://www.510kdatabase.net/k023131/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lambda, Antigen, Antiserum, Control (DEH)
Date received	Sep 9, 2002
Decision date	Jan 21, 2003
Days to decision	134 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/k023131/> 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 June 28, 2026