

**K010146 ENA EIA KIT RANGE**Mar 1, 2001  
43 days to decisionK010146 · Product code: **LLL** · Immunology  
Source: <https://www.510kdatabase.net/k010146/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                          |
| Submission type       | Traditional   |
| Device classification | Extractable Antinuclear Antibody, Antigen And Control (LLL) |
| Date received         | Jan 17, 2001  |
| Decision date         | Mar 1, 2001   |
| Days to decision      | 43 days   |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010146/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026