

**K002561 SHEEP ANTI-HUMAN IGD IMMUNOFIXATION GRADE  
KIT**Oct 26, 2000  
70 days to decisionK002561 · Product code: **CZJ** · Immunology  
Source: <https://www.510kdatabase.net/k002561/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Igd, Antigen, Antiserum, Control (CZJ) |
| Date received         | Aug 17, 2000                           |
| Decision date         | Oct 26, 2000                           |
| Days to decision      | 70 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/k002561/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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