

K100455 SPAPLUS ANALYZERSep 3, 2010
198 days to decisionK100455 · Product code: **DBI** · Immunology
Source: <https://www.510kdatabase.net/k100455/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Complement C4, Antigen, Antiserum, Control (DBI) |
| Date received | Feb 17, 2010 |
| Decision date | Sep 3, 2010 |
| Days to decision | 198 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | The Binding Site |
| Location | Santa Monica, CA, US |
| Contact | JAY GELLER |
| 510(k) history | 10 submissions · 10 cleared · 2004-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100455/> 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 7, 2026