

K984163 ANTI-TPO EIA DIAGNOSTIC TEST KITFeb 2, 1999
74 days to decisionK984163 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k984163/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Thyroid Autoantibody (JZO) |
| Date received | Nov 20, 1998 |
| Decision date | Feb 2, 1999 |
| Days to decision | 74 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 |

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