

K981521 AIA-PACK TPOAB ASSAYOct 8, 1998
163 days to decisionK981521 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k981521/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Thyroid Autoantibody (JZO) |
| Date received | Apr 28, 1998 |
| Decision date | Oct 8, 1998 |
| Days to decision | 163 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Tosoh Medics, Inc. |
| Location | Washington, DC, US |
| Contact | LON ROBINSON |
| 510(k) history | 41 submissions · 41 cleared · 1990-2002 |

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