

**K935049 ELEGANCE NEONATAL TSH ELISA**Oct 3, 1994  
348 days to decisionK935049 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k935049/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Oct 20, 1993
Decision date	Oct 3, 1994
Days to decision	348 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bioclone Australia Pty , Ltd.</b>
Location	Washington, DC, US
Contact	BRUCE F MACKLER
510(k) history	10 submissions · 10 cleared · 1990-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k935049/> 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 30, 2026