

**K913963 IMMUCHEM NEONATAL TSH-MP ELISA**Dec 13, 1991  
99 days to decisionK913963 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k913963/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Sep 5, 1991
Decision date	Dec 13, 1991
Days to decision	99 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Icn Biomedicals, Inc.</b>
Location	Carson, CA, US
Contact	JEFFREY C TRAVIS
510(k) history	11 submissions · 11 cleared · 1988-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913963/> 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 28, 2026