

**K962464 SCANTIBODIES LABORATORY TSH  
IMMUNORADIOMETRIC ASSAY (IRMA)(COATED TUBE  
TECHNOLOGY)**Oct 8, 1996  
105 days to decisionK962464 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k962464/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Jun 25, 1996
Decision date	Oct 8, 1996
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Scantibodies Laboratory, Inc.</b>
Location	Santee, CA, US
Contact	RICHARD LENART
510(k) history	19 submissions · 19 cleared · 1995-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k962464/>; 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 29, 2026