

**K942661 AQUALITE TSH BIOLUMINESCENT IMMUNOASSAY  
KIT**Jan 17, 1995  
225 days to decisionK942661 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k942661/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Jun 6, 1994
Decision date	Jan 17, 1995
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sealite Sciences, Inc.</b>
Location	Bogart, GA, US
Contact	DAVID F SMITH
510(k) history	11 submissions · 11 cleared · 1994-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k942661/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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