

K052301 FASTPACK TSH IMMUNOASSAYJan 4, 2006
135 days to decisionK052301 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k052301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Aug 22, 2005
Decision date	Jan 4, 2006
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Qualigen, Inc.
Location	Carlsbad, CA, US
Contact	DOROTHY PETERSON
510(k) history	15 submissions · 15 cleared · 2000-2019

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