

K101390 FASTPACK TSH IMMUNOASSAYAug 13, 2010
88 days to decisionK101390 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k101390/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	May 17, 2010
Decision date	Aug 13, 2010
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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