

**K952211 AMERLITE TSH-30 ULTRASENSITIVE ASSAY
(LAN.0010Q/2010Q)**Jul 14, 1995
64 days to decisionK952211 · Product code: JLW · Chemistry
Source: <https://www.510kdatabase.net/k952211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	May 11, 1995
Decision date	Jul 14, 1995
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Johnson & Johnson Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	BRADFORD M SPRING
510(k) history	33 submissions · 33 cleared · 1995-1998

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