

K041014 TSH-CTK-3 IRMAJul 14, 2004
85 days to decisionK041014 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k041014/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Apr 20, 2004
Decision date	Jul 14, 2004
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DiaSorin, Inc.
Location	Ellicott City, MD, US
Contact	DAVID M IKEDA
510(k) history	71 submissions · 70 cleared · 1998-2026

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