

K160541 Automated Immunoassay System HISCL -800, HISCL TSH Assay Kit, HISCL TSH Calibrator, HISCL Immuno Multi ControlOct 21, 2016
238 days to decisionK160541 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k160541/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Feb 26, 2016
Decision date	Oct 21, 2016
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sysmex America, Inc.
Location	Mundelein, IL, US
Contact	Michelle Parker
510(k) history	30 submissions · 30 cleared · 2003-2025

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