

**K160647 IMMULITE 2000 Third Generation TSH, IMMULITE 2000
Free T4**May 31, 2016
85 days to decisionK160647 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k160647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Mar 7, 2016
Decision date	May 31, 2016
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	Matthew Gee
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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