

K251543 Atellica® IM TSH3-Ultra II (TSH3ULII)Feb 6, 2026
262 days to decisionK251543 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k251543/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	May 20, 2025
Decision date	Feb 6, 2026
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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