

**K243570 Dimension LOCI Thyroid Stimulating Hormone Flex reagent cartridge (TSHL)**Apr 25, 2025  
158 days to decisionK243570 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k243570/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Nov 18, 2024
Decision date	Apr 25, 2025
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Dimension LOCI Free Thyroxine Flex reagent cartridge (FT4L)

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics</b>
Location	Newark, DE, US
Contact	Yevgenia Sarkisian
510(k) history	92 submissions · 92 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243570/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026