

**K100778 DIMENSION EXL LOCI THYROID CALIBRATOR,
MODEL RC 610A**

May 5, 2010
47 days to decision

K100778 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k100778/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Mar 19, 2010
Decision date	May 5, 2010
Days to decision	47 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	ROSE T MARINELLI
510(k) history	92 submissions · 92 cleared · 2008-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k100778/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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