

**K100344 DIMENSION VISTA LOCI CA 15-3 FLEX REAGENT
CARTRIDGE, DIMENSION VISTA LOCI 7 CALIBRATOR,
MODELS: K6456 AND KC605**Apr 18, 2011
437 days to decisionK100344 · Product code: **MOI** · Immunology
Source: <https://www.510kdatabase.net/k100344/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Feb 5, 2010
Decision date	Apr 18, 2011
Days to decision	437 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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