

**K100321 DIMENSION VISTA LOCI CA 125 FLEX REAGENT
CARTRIDGE, AND DIMENSIONS VISTA LOCI 6 CAL,
MODEL#'S K6455, AND KC604**Apr 12, 2011
432 days to decisionK100321 · Product code: LTK · Immunology
Source: <https://www.510kdatabase.net/k100321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Feb 4, 2010
Decision date	Apr 12, 2011
Days to decision	432 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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