

K100375 DIMENSION VISTA LOCI CA 19-9 FLEX REAGENT CARTRIDGE, AND DIMENSION LOCI7 CALIBRATOR WITH MODEL(S) K6457, AND KC604Apr 6, 2011
418 days to decisionK100375 · Product code: **NIG** · Immunology
Source: <https://www.510kdatabase.net/k100375/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Carbohydrate Antigen (ca19-9), For Monitoring And Management Of Pancreatic Cancer (NIG)
Date received	Feb 12, 2010
Decision date	Apr 6, 2011
Days to decision	418 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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