

**K090330 DIMENSION VISTA ENZYMATIC CREATININE FLEX
REAGENT CARTRIDGE, AND ENZYMATIC CREATININE
CALIBRATOR, MODELS K1270, KC270**May 22, 2009
101 days to decisionK090330 · Product code: JFY · Chemistry
Source: <https://www.510kdatabase.net/k090330/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Feb 10, 2009
Decision date	May 22, 2009
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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