FDA 510(k) Premarket Notification

K102045 DIMENSION VISA HBA1C, MODEL K3105A

CLEARED

Feb 14, 2011
208 days to decision

K102045 · Product code: **LCP** · Chemistry
Source: https://www.510kdatabase.net/k102045/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jul 21, 2010
Decision date	Feb 14, 2011
Days to decision	208 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Heatlhcare Diagnostics, Inc.**
Location	New York, NY, US
Contact	ANNA-MARIE K ENNIS
510(k) history	3 submissions · 3 cleared · 2010-2011

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k102045/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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