

**K083462 DIMENSION VISTA SYSTEM ENZYME 5 CALIBRATOR,
MODEL KC350**

Feb 27, 2009
95 days to decision

K083462 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k083462/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Nov 24, 2008
Decision date	Feb 27, 2009
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k083462/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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