

K140790 Dimension Vista Chemistry 1 Calibrator (CHEM 1 CAL), Dimension Vista Magnesium Flex reagent cartridge (MG)Jun 15, 2015
441 days to decisionK140790 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k140790/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Mar 31, 2014
Decision date	Jun 15, 2015
Days to decision	441 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.netDevice record: <https://www.510kdatabase.net/k140790/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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