

K103612 DIMENSION VISA ENZ 2 CALJan 25, 2011
47 days to decisionK103612 · Product code: **JIX** · Chemistry
Source: <https://www.510kdatabase.net/k103612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Dec 9, 2010
Decision date	Jan 25, 2011
Days to decision	47 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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