

**K963543 SIGMA DIAGNOSTICS CX -3 CALIBRATION
STANDARD, LEVEL 2**Oct 30, 1996
56 days to decisionK963543 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k963543/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Sep 4, 1996
Decision date	Oct 30, 1996
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963543/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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