

**K963533 SIGMA DIAGNOSTIC CX -3 CALIBRATION STANDARD
LEVEL 1**

Oct 29, 1996
55 days to decision

K963533 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k963533/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Sep 4, 1996
Decision date	Oct 29, 1996
Days to decision	55 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

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Device record: <https://www.510kdatabase.net/k963533/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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