

K090283 CALIBRATOR 1,2, AND 3 MODELS: GEN-CAL1, GEN-CAL2, AND GEN-CAL3Jun 5, 2009
120 days to decisionK090283 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k090283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Feb 5, 2009
Decision date	Jun 5, 2009
Days to decision	120 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Genchem, Inc.
Location	Brea, CA, US
Contact	JAMES M HENNEMAN
510(k) history	8 submissions · 8 cleared · 2004-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090283/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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