

**K944063 FLUORESCENCE POLARIZATION IMMUNOASSAY
CARBAMAZEPINE**Nov 10, 1994
83 days to decisionK944063 · Product code: **LGI** · Chemistry
Source: <https://www.510kdatabase.net/k944063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Carbamazepine (LGI)
Date received	Aug 19, 1994
Decision date	Nov 10, 1994
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	HOYLE D HILL
510(k) history	164 submissions · 164 cleared · 1984-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944063/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026