

K941712 COBAS-FP REAGENTS AND CALIBRATORSJun 13, 1994
68 days to decisionK941712 · Product code: **LGJ** · Toxicology
Source: <https://www.510kdatabase.net/k941712/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Amibacin (LGJ)
Date received	Apr 6, 1994
Decision date	Jun 13, 1994
Days to decision	68 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	CAROL L KRIEGER
510(k) history	296 submissions · 296 cleared · 1983-1999

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