

K941440 COBAS-FP QUINIDINE REAGENTS AND CALIBRATORSJul 6, 1994
104 days to decisionK941440 · Product code: **LBZ** · Toxicology
Source: <https://www.510kdatabase.net/k941440/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Quinidine (LBZ)
Date received	Mar 24, 1994
Decision date	Jul 6, 1994
Days to decision	104 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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