

**K942847 COBAS(R)-FP REAGENT FOR
PROCAINAMIDE/CALIBRATOR**Dec 2, 1994
169 days to decisionK942847 · Product code: LAR · Toxicology
Source: <https://www.510kdatabase.net/k942847/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Procaïnamide (LAR)
Date received	Jun 16, 1994
Decision date	Dec 2, 1994
Days to decision	169 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942847/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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