

**K852320 COBAS FP REAGEN FOR PROCAINAMIDE & PRO  
CALIBRATOR**Jul 9, 1985  
39 days to decisionK852320 · Product code: LAR · Toxicology  
Source: <https://www.510kdatabase.net/k852320/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Procaïnamide (LAR)
Date received	May 31, 1985
Decision date	Jul 9, 1985
Days to decision	39 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

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Company	<b>Roche Diagnostic Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	DONALD KAFADER
510(k) history	296 submissions · 296 cleared · 1983-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k852320/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 23, 2026