

**K936131 COBAS-FP REAGENT FOR PHENYTOIN AND COBA-FP PHENYTOIN CALIBRATORS**Mar 11, 1994  
78 days to decisionK936131 · Product code: **LGR** · Toxicology  
Source: <https://www.510kdatabase.net/k936131/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Diphenylhydantoin (total) (LGR)
Date received	Dec 23, 1993
Decision date	Mar 11, 1994
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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