

**K952555 COBAS-FP APPLICATION FOR FREE PHENYTOIN,  
COBAS-FP PHENYTOIN CALIBRATORS, & CONTROLS**Jul 31, 1995  
59 days to decisionK952555 · Product code: **MOJ** · Chemistry  
Source: <https://www.510kdatabase.net/k952555/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Diphenylhydantoin (free) (MOJ)
Date received	Jun 2, 1995
Decision date	Jul 31, 1995
Days to decision	59 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	RITA SMITH
510(k) history	296 submissions · 296 cleared · 1983-1999

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