

**K852318 COBAS FP REAGEN FOR PRIMIDONE & PRIMI  
CALIBRATORS**Jun 25, 1985  
25 days to decisionK852318 · Product code: **LFT** · Toxicology  
Source: <https://www.510kdatabase.net/k852318/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Primidone (LFT)
Date received	May 31, 1985
Decision date	Jun 25, 1985
Days to decision	25 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/k852318/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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