# K852318 COBAS FP REAGEN FOR PRIMIDONE & PRIMI CALIBRATORS

**CLEARED**

Jun 25, 1985
25 days to decision

K852318 · 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

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