

**K872397 COBAS FP REAGENTS FOR PHENO & COBAS FP
PHENO CALI.**Jul 21, 1987
29 days to decisionK872397 · Product code: **LGQ** · Toxicology
Source: <https://www.510kdatabase.net/k872397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Phenobarbital (LGQ)
Date received	Jun 22, 1987
Decision date	Jul 21, 1987
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

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