

K843825 COBAS REAGENTS PHENOBARBITAL & PHENOBARFeb 1, 1985
126 days to decisionK843825 · Product code: **LGQ** · Toxicology
Source: <https://www.510kdatabase.net/k843825/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Phenobarbital (LGQ)
Date received	Sep 28, 1984
Decision date	Feb 1, 1985
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

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