

K843824 COBAS FP REAGENTS FOR PHENYTOIN & CALIBRFeb 1, 1985
126 days to decisionK843824 · Product code: **LGR** · Toxicology
Source: <https://www.510kdatabase.net/k843824/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Diphenylhydantoin (total) (LGR)
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
Contact	GRIFFIN FITZGERALD
510(k) history	296 submissions · 296 cleared · 1983-1999

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