

K871484 COBAS FP REAGENTS FOR THEOPHYLLINE & CALIBRATORSMay 28, 1987
43 days to decisionK871484 · Product code: **LGS** · Chemistry
Source: <https://www.510kdatabase.net/k871484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Theophylline (LGS)
Date received	Apr 15, 1987
Decision date	May 28, 1987
Days to decision	43 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k871484/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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