

K852319 COBAS FP REAGENTS FOR NAPA AND NAPA CALIBRATORSJun 25, 1985
25 days to decisionK852319 · Product code: **LAN** · Toxicology
Source: <https://www.510kdatabase.net/k852319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, N-acetylprocainamide (LAN)
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

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