

**K871680 MODIFIED COBAS FP REAGENTS FOR NAPA AND CALIBRATOR**Jun 8, 1987  
40 days to decisionK871680 · Product code: **LAN** · Toxicology  
Source: <https://www.510kdatabase.net/k871680/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, N-acetylprocainamide (LAN)
Date received	Apr 29, 1987
Decision date	Jun 8, 1987
Days to decision	40 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k871680/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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