

K983812 NAPA EIA ASSAYNov 16, 1998
19 days to decisionK983812 · Product code: **LAN** · Toxicology
Source: <https://www.510kdatabase.net/k983812/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, N-acetylprocainamide (LAN)
Date received	Oct 28, 1998
Decision date	Nov 16, 1998
Days to decision	19 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diagnostic Reagents, Inc.
Location	Walker, MI, US
Contact	YUH-GENG TSAY
510(k) history	66 submissions · 66 cleared · 1982-1998

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