

K860140 STRATUS N-ACE (NAPA) FLUOROMETRIC ENZYME/IMMUNO.Feb 6, 1986
23 days to decisionK860140 · Product code: LAN · Toxicology
Source: <https://www.510kdatabase.net/k860140/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, N-acetylprocainamide (LAN)
Date received	Jan 14, 1986
Decision date	Feb 6, 1986
Days to decision	23 days
Third-party review	No

APPLICANT

Company	American Dade
Location	Mchenry, IL, US
Contact	KAREN DARCY
510(k) history	149 submissions · 149 cleared · 1980-1987

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k860140/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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