

K853548 STRATUS PROCAINAMIDE FLUOROMETRIC ENZYME IMMUNOASSSep 18, 1985
23 days to decisionK853548 · Product code: **LCM** · Chemistry
Source: <https://www.510kdatabase.net/k853548/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phencyclidine (LCM)
Date received	Aug 26, 1985
Decision date	Sep 18, 1985
Days to decision	23 days
Third-party review	No

APPLICANT

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

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