

K832447 STRATUS CARBAMAZEPINE FLUROMETRICSep 12, 1983
49 days to decisionK832447 · Product code: **KLT** · Chemistry
Source: <https://www.510kdatabase.net/k832447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Jul 25, 1983
Decision date	Sep 12, 1983
Days to decision	49 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k832447/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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