

K830701 STRATUS PHENOBARBITAL FLUOROMETRIC ENZMay 13, 1983
67 days to decisionK830701 · Product code: **LET** · Toxicology
Source: <https://www.510kdatabase.net/k830701/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Phenobarbital (LET)
Date received	Mar 7, 1983
Decision date	May 13, 1983
Days to decision	67 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/k830701/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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