

K832965 STRATUS THEOPHYLLINE ASSAYDec 30, 1983
120 days to decisionK832965 · Product code: **KLS** · Chemistry
Source: <https://www.510kdatabase.net/k832965/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Theophylline (KLS)
Date received	Sep 1, 1983
Decision date	Dec 30, 1983
Days to decision	120 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/k832965/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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