

**K831154 STRATUS PHENYTOIN FLUOROMETRIC ENZYME**May 16, 1983  
38 days to decisionK831154 · Product code: **LES** · Immunology  
Source: <https://www.510kdatabase.net/k831154/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Diphenylhydantoin (LES)
Date received	Apr 8, 1983
Decision date	May 16, 1983
Days to decision	38 days
Third-party review	No

**APPLICANT**

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

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Device record: <https://www.510kdatabase.net/k831154/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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