

**K862818 STRATUS FERRITIN FLUOROMETRIC ENZYME  
IMMUNOASSAY**Aug 19, 1986  
26 days to decisionK862818 · Product code: **JJE** · Chemistry  
Source: <https://www.510kdatabase.net/k862818/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Chemistry (photometric, Discrete), For Clinical Use (JJE)
Date received	Jul 24, 1986
Decision date	Aug 19, 1986
Days to decision	26 days
Third-party review	No

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k862818/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026