

**K850570 STRATUS HCG FLUOROMETRIC ENZYME  
IMMUNOASSAY**Apr 2, 1985  
48 days to decisionK850570 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k850570/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Feb 13, 1985
Decision date	Apr 2, 1985
Days to decision	48 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/k850570/> 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