

**K831177 STRATUS DIGOXIN FLUOROMETRIC ENZYME IMM-**May 17, 1983  
36 days to decisionK831177 · Product code: **KXT** · Immunology  
Source: <https://www.510kdatabase.net/k831177/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Enzyme Immunoassay, Digoxin (KXT)  |
| Date received         | Apr 11, 1983                       |
| Decision date         | May 17, 1983                       |
| Days to decision      | 36 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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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k831177/> 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