

**K820397 AMERIFLUOR THEOPHYLLINE FLUORESCENT IMM**Mar 2, 1982  
19 days to decisionK820397 · Product code: LER · Chemistry  
Source: <https://www.510kdatabase.net/k820397/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Traditional                                 |
| Device classification | Fluorescent Immunoassay, Theophylline (LER) |
| Date received         | Feb 11, 1982                                |
| Decision date         | Mar 2, 1982                                 |
| Days to decision      | 19 days                                     |
| Third-party review    | No  |

**APPLICANT**

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| Company        | <b>American Diagnostic Corp.</b>        |
| Location       | Mchenry, IL, US                         |
| 510(k) history | 39 submissions · 39 cleared · 1980-2017 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k820397/> 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 June 1, 2026